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Declaration of Conformity CE

Product Name:	**Model/Type:**
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

Medica Corporation
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Representative

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Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design, Development, Manufacture, Service, Installation and Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0089217

Initial Certification Date:
2019-04-19

Certification Effective Date:
2019-04-19

Certification Expiry Date:
2022-04-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14
Expiry Date: 2024-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Effective Date: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

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Thromboplastin L

REF 5265HL
REF 5265L
REF 5267L

CE IVD

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HL-2-3035P 2015/10 (1)

Thromboplastin L
Instructions for use — en

INTENDED PURPOSE

The Thromboplastin L kit is intended for carrying out clot based haemostasis assays.

The first standardised one-stage prothrombin time test was developed by Dr. Armand Quick in 1935. It has now become the basic coagulation screening test for the diagnosis of congential and acquired deficiencies of clotting factors from the extrinsic pathway (factors II, V, VII and X)[1,2]. It is also used for the induction and monitoring of oral anticoagulant therapy[3,4] and can be used to assess the protein synthesis capability of the liver in chronic or acute hepatic disorders.
Thromboplastin L is of rabbit brain origin but resembles human preparations in its low International Sensitivity Index (ISI). The ISI of Thromboplastin L is approximately 1.1 and is calibrated against the WHO international reference preparation[5].
Thromboplastin L is particularly suited to the monitoring of oral anticoagulant therapy and, in conjunction with the appropriate factor deficient plasma, the measurement of factor activity in the extrinsic pathway. Tissue thromboplastin, in the presence of calcium ions, is an activator which initiates the extrinsic pathway of coagulation. When a mixture of tissue thromboplastin and calcium ions is added to normal citrated plasma, the clotting mechanism is activated, leading to a fibrin clot. If a deficiency exists within the extrinsic pathway, the time required for clot formation will be prolonged depending on the severity of the deficiency.

WARNINGS AND PRECAUTIONS

The reagents contained in this kit are for *in vitro* diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all kit components. Refer to the product safety declaration for the link to appropriate hazard and precautionary statements where applicable. Dispose of components in accordance with local regulations.

COMPOSITION

Composition	Content	Description	Preparation
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Liquid Rabbit Brain Thromboplastin containing Calcium Chloride, stabilisers and preservatives.	The liquid, calcified thromboplastin is ready-for-use. No further calcium is required to carry out standard PT Assays. The contents of the vial should be mixed well before use. (5 minutes on roller).

Each kit contains Instructions For Use.

Each kit contains lot specific reference values insert.

ITEMS REQUIRED BUT NOT PROVIDED

The below products can be used in conjunction with Thromboplastin L:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

STORAGE, SHELF-LIFE AND STABILITY

Unopened reagents are stable until the given expiry date when stored under conditions indicated on the vial or kit label.

Thromboplastin L	Opened vials are stable for 2 months at $^{+}$2 –$^{+}$8°C, 5 days at $^{+}$15°C (on-board Sysmex CA-1500) and 6 hours at $^{+}$37°C (on-board AC-4 including reagent container and cap). A shift-use stability of 7 days (Sysmex CA-1500) can be achieved. DO NOT FREEZE. Large clumps of particles or changes in expected values may indicate product deterioration.

SAMPLE COLLECTION AND PREPARATION

Plastic or siliconised glass should be used throughout. Blood (9 parts) should be collected into 3.2% or 3.8% sodium citrate anticoagulant (1 part). Separate plasma after centrifugation at 1500 x g for 15 minutes. Plasma should be kept at $^{+}$18 –$^{+}$24°C. Testing should be completed within 4 hours of sample collection, or plasma can be stored frozen at -20°C for 2 weeks or -70°C for 6 months. Thaw quickly at $^{+}$37°C prior to testing. Do not keep at $^{+}$37°C for more than 5 minutes[6].

PROCEDURE

For accurate INR reporting, it is recommended to determine the laboratory specific ISI of the reagent with the testing system in use. The Helena Biosciences Europe ISI Calibrant Plasma Set (REF 5519) is recommended for this purpose[7,8]. This should be performed for each new reagent batch. The Helena Biosciences Europe INR Reference Set (REF 5490) should be used to check for shifts in the local system ISI which have been noted with changes in laboratory temperature and post instrument servicing, amongst other local variances.

Manual Method

1. Mix sufficient Thromboplastin L to complete the anticipated testing for the day and incubate at $^{+}$37°C for no more than 4 hours.
2. Pre-warm 0.1 mL of the test plasma at $^{+}$37°C for 2 minutes.
3. Add 0.2 mL of freshly mixed thromboplastin reagent to the plasma while simultaneously starting a stopwatch.
4. Note the time for clot formation to the nearest 0.1 seconds.

Automated Method

Refer to the appropriate instrument operator manual for detailed instructions or contact Helena Biosciences Europe for instrument specific application guides.

INTERPRETATION OF RESULTS

Results should be reported to the nearest 0.1 seconds and duplicates should agree within 5% of each other. %PT values can be interpolated from the calibration graph (%PT of PT Calibration plasmas versus measured clot time), which should be a straight line when plotted on log-log graph paper.

INR values can be calculated using the following formula: INR = (PT Time Patient / Mean Normal PT Time)^{ISI}

For clear guidance on the indications for and management of patients on warfarin, please refer to The British Society for Haematology, for their most current edition of 'Guidelines on oral anticoagulation with warfarin'. At time of printing this is the 2011 fourth edition[9].

LIMITATIONS

The use of serial dilutions of a reference plasma for the %PT curve is not recommended as this can lead to discrepancies caused by the low fibrinogen in the reference plasma dilutions which are not reflected in patient samples having predominantly normal fibrinogen levels. Helena Biosciences Europe advise use of the 5504R %PT/Direct INR kit for this purpose.

QUALITY CONTROL

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
Helena Biosciences Europe supplies the following controls available for use with this product:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

REFERENCE VALUES

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own reference ranges. This is particularly important for local ISI calibration. Using the Sysmex series of instruments, normal values ranging from 11.50 - 14.60 seconds; 0.930 - 1.160 INR; 79.10 - 112.80 %PT are typical.

PERFORMANCE CHARACTERISTICS

The following performance characteristics have been determined by Helena Biosciences Europe or their representatives using a Sysmex CA-1500 coagulation instrument. Each laboratory should establish its own performance data.

Reproducibility

Sample	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Repeatability	0.07	0.59	0.24	1.09	0.45	1.11
Between-run	0.10	0.83	0.16	0.75	0.49	1.20
Between-day	0.04	0.32	0.06	0.27	0.25	0.62
Within-device / Laboratory	0.12	1.07	0.29	1.35	0.72	1.75

Interferences

Helena Thromboplastin L is insensitive to Heparin levels of up to 2 U/mL. Using a 5% interference threshold, there is no significant interference from Haemoglobin at concentrations up to 10 g/L. Using a 5% interference threshold, there is no significant interference from Bilirubin at concentrations up to 0.5 g/L for Thromboplastin L. Lipid interference testing demonstrates that lipid levels do not directly affect the clot time of the reagent up to 3.75g/L. Lipid concentrations in excess of this prevent clot detection.

Method Comparison

Comparison of clot time in seconds and INR values were determined using Thromboplastin L and Thromboplastin LI on 268 samples. The following correlations were obtained:

Thromboplastin L (Seconds) = 0.9911x + 0.1038	r^2 = 0.9941	n = 268
Thromboplastin L (INR) = 0.9853x + 0.0261	r^2 = 0.9500	n = 268

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3. Hirsh J, Poller L, Deykin D, Levine J, Dalen JE (1989) Optimal Therapeutic Range for Oral Anticoagulants, *Chest,* **95:** 5S-11S.
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6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5.
7. Poller L., Triplett DA, Hirsh J, Carroll J, Clarke K (1995) The value of plasma calibrants in correcting coagulometer effects on International Normalised Ratios (INR): An international multicentre study, *Amer. J. Clin. Pathol,* **103:** 358-365.
8. Poller L, Triplett DA, Hirsh J, Carroll J, Clarke K (1995) A comparison of lyophilised artificially depleted plasmas and lyophilised plasmas from warfarin treated patients in correcting for coagulometer effects on International Normalised Ratios, *Amer. J. Clin. Pathol*, **103:** 366-371.
9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Thromboplastin L
Fiche technique — fr

UTILISATION

Le kit Thromboplastin L est destiné à la réalisation des analyses de l'hémostase basées sur la formation de caillots.

La première méthode de détermination standardisée du temps de prothrombine en une étape a été développée en 1935 par le Dr. Armand Quick. Cette méthode de Quick constitue désormais l'analyse de base de la coagulation servant à diagnostiquer des anomalies des facteurs de coagulation, congénitales ou acquises, à partir de la voie extrinsèque (facteurs II, V, VII et X)[1,2]. Elle sert aussi à l'induction et au monitorage des thérapies avec anticoagulants oraux[3,4] et elle peut être utilisée pour évaluer la capacité de synthèse des protéines du foie chez les patients souffrants de troubles hépatiques chroniques ou aigus.
Le Thromboplastin L provient de cerveaux de lapin mais il ressemble au BCT humain en raison de son indice de sensibilité international (ISI) faible. L'ISI du Thromboplastin L est d'environ 1,1 et est étalonné en comparaison avec la préparation internationale de référence de l'OMS[5]. Le Thromboplastin L convient tout particulièrement au monitorage des thérapies avec anticoagulants oraux et, utilisé conjointement au plasma carencé en un facteur approprié, à la détermination de l'activité du facteur de la voie extrinsèque. La thromboplastine tissulaire, en présence d'ions calcium, est un activateur qui démarre la voie extrinsèque de la coagulation. Quand un mélange de thromboplastine tissulaire et d'ions calcium est ajouté à un plasma citraté normal, le processus de coagulation, qui doit conduire à la production d'un caillot fibreux, s'active. Si la voie extrinsèque présente une anomalie, le temps nécessaire à la formation du caillot est allongé suivant la gravité du trouble de la coagulation.

AVERTISSEMENTS ET PRÉCAUTIONS

Les réactifs du kit sont à usage diagnostique *in vitro* uniquement – NE PAS INGÉRER. Porter un équipement de protection individuelle approprié lors de la manipulation de tous les composants du kit. Consulter la fiche de données de sécurité du produit pour obtenir le lien vers les phrases de risque et les conseils de prudence le cas échéant. Éliminer les composants conformément aux églementations locales.

COMPOSITION

Composant	Contient	Description	Préparation
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Thromboplastine liquide de cerveau de lapin contenant du chlorure de calcium, des stabilisateurs et des conservateurs.	La thromboplastine liquide calcifiée est prête à l'emploi. Aucun calcium supplémentaire n'est nécessaire pour réaliser des déterminations standard du TP. Le contenu du flacon doit être bien mélangé avant utilisation (5 minutes sur un mélangeur à rouleaux).

Chaque kit contient une fiche technique.

Chaque kit contient valeurs de référence spécifiques du lot.

MATÉRIEL NÉCESSAIRE NON FOURNI

Les produits ci-dessous peuvent être utilisés en conjonction avec la Thromboplastin L :

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

CONSERVATION, DURÉE DE VIE UTILE ET STABILITÉ

Les flacons de réactif non ouverts sont stables jusqu'à la date de péremption indiquée s'ils sont conservés dans les conditions indiquées sur l'étiquette du kit ou du flacon.

Thromboplastin L	Les flacons ouverts sont stables pendant 2 mois à $^{+}$2 °C – $^{+}$8 °C, pendant 5 jours à $^{+}$15 °C (à bord du Sysmex CA-1500) et pendant 6 heures à $^{+}$37 °C (à bord de l'AC-4, récipient de réactif et capuchon inclus). Il est possible d'obtenir une stabilité de période de travail de 7 jours (Sysmex CA-1500). NE PAS CONGELER. La présence de d'amas de particules ou un écart par rapport aux valeurs prévues indique une détérioration du produit.

PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS

Utiliser tout au long du prélèvement du plastique ou du verre siliconé. Mélanger 9 volumes de sang et 1 volume de citrate de sodium à 3,2% ou 3,8%. Séparer le plasma après centrifugation à 1500 x g pendant 15 minutes. Conserver le plasma entre $^{+}$18 –$^{+}$24°C. L'analyse doit être terminée dans les 4 heures suivant le prélèvement de l'échantillon ; sinon, il est possible de congeler le plasma 2 semaines à -20°C ou 6 mois à -70°C. Décongeler rapidement à $^{+}$37°C avant de réaliser l'analyse. Ne pas laisser à $^{+}$37°C plus de 5 minutes[6].

PROCÉDURE

Pour obtenir un RNI (rapport normalisé international) précis, il est recommandé à chaque laboratoire de déterminer l'ISI spécifique du réactif avec le système d'analyse utilisé. Il est conseillé d'utiliser le ISI Calibrant Plasma Set Helena Biosciences Europe (REF 5519) pour cela[7,8]. Cette opération doit être réalisée pour chaque nouveau lot de réactif. Le kit RNI de référence Helena Biosciences Europe (REF 5490) doit être utilisé pour vérifier l'existence d'un décalage de l'ISI du système local déterminé en raison d'une variation de la température du laboratoire, suite à une opération de maintenance réalisée sur l'instrument ou toute autre variable locale.

Méthode Manuelle

1. Mélanger du Thromboplastin L en quantité suffisante pour réaliser les analyses prévues dans la journée et incuber à $^{+}$37 °C pendant 4 heures au maximum.
2. Préchauffer 0,1 mL de plasma à $^{+}$37°C pendant 2 minutes.
3. Ajouter 0,2 mL de réactif de thromboplastine fraîchement mélangé au plasma et démarrer à ce moment un chronomètre.
4. Relever le temps de formation du caillot en arrondissant au dixième de seconde.

Méthodes Automatisées

Consulter le manuel d'utilisation de l'instrument approprié pour obtenir des instructions détaillées ou contacter Helena Biosciences Europe pour obtenir des notes d'application spécifiques à l'instrument.

INTERPRÉTATION DES RÉSULTATS

Les résultats doivent être indiqués en arrondissant au dixième de seconde et l'écart maximal entre eux est de 5%. Il est possible d'interpoler les valeurs de %TP à partir de la courbe d'étalonnage (%TP des plasmas d'étalonnage du TP par rapport au temps de coagulation mesuré), qui doit correspondre à une ligne droite quand elle est représentée sur du papier logarithmique.

La formule suivante permet de calculer les valeurs du RNI: RNI = (Temps TP patient / Temps TP moyen normal)^{ISI}

Pour obtenir des informations claires quant aux indications et à la prise en charge des patients sous warfarine, consulter la British Society for Haematology pour obtenir la dernière édition des Guidelines on oral anticoagulation with warfarin (Recommandations relatives à l'anticoagulothérapie orale avec la warfarine). Au moment de l'impression du présent document, il s'agit de la quatrième édition de 2011[9].

LIMITES

Il est déconseillé de réaliser des dilutions du plasma de référence pour la courbe de %TP, car cela risquerait d'entraîner des divergences dues au faible taux de fibrinogène présent dans les dilutions du plasma de référence, ce qui ne serait pas représentatif des échantillons patients qui ont principalement des taux de fibrinogène normaux. Helena Biosciences Europe conseille l'utilisation du kit 5504R %PT/Direct INR dans ce but.

CONTRÔLE QUALITÉ

Chaque laboratoire doit établir un programme de contrôle qualité. Les plasmas de contrôle, normaux et anormaux, doivent être testés avant chaque lot d'échantillons patients afin de s'assurer que l'instrument et l'opérateur offrent des performances satisfaisantes. Si les contrôles ne donnent pas les résultats prévus, les résultats du patient doivent être considérés comme non valables.
Helena Biosciences Europe distribue les contrôles suivants à utiliser avec ce produit:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALEURS DE RÉFÉRENCE

Les valeurs de référence peuvent varier d'un laboratoire à l'autre suivant les techniques et les systèmes utilisés. C'est pour cette raison qu'il appartient à chaque laboratoire de déterminer ses propres plages de référence. Ceci est particulièrement important pour l'étalonnage de l'ISI local. Avec les instruments de la série Sysmex, l'intervalle type des valeurs normales est de 11,50 - 14,60 secondes; 0.930 - 1.160 INR; 79.10 - 112.80 %PT .

CARACTÉRISTIQUES DE PERFORMANCES

Helena Biosciences Europe ou ses mandataires ont déterminé les caractéristiques de performance suivantes en utilisant un instrument de coagulation Sysmex CA-1500. Chaque laboratoire doit établir ses propres données de performance.

Reproductibilité

Échantillon	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Répétabilité	0,07	0,59	0,24	1,09	0,45	1,11
Inter-séries	0,10	0,83	0,16	0,75	0,49	1,20
Inter-jours	0,04	0,32	0,06	0,27	0,25	0,62
Intra-dispositif/laboratoire	0,12	1,07	0,29	1,35	0,72	1,75

Interférences

Thromboplastin L (ISI faible) d'Helena ne présente pas d'interférences avec un taux d'héparine jusqu'à 2 U/mL. En utilisant un seuil d'interférence de 5 %, il n'y a pas d'interférences significatives de l'hémoglobine à une concentration jusqu'à 10 g/L. En utilisant un seuil d'interférence de 5 %, il n'y a pas d'interférences significatives de la bilirubine à une concentration jusqu'à 0,5 g/L pour la Thromboplastin L. Une évaluation de l'interférence des lipides montre que les taux de lipides n'affectent pas le temps de coagulation du réactif jusqu'à 3,75 g/L. Une concentration en lipides dépassant cette limite empêche la détection du caillot.

Comparaison de la méthode

Des comparaisons du temps de coagulation en secondes et en valeurs de RNI ont été déterminées en utilisant les produits Thromboplastin L et Thromboplastin LI avec 268 échantillons. Les corrélations suivantes ont été obtenues:

Thromboplastin L (seconde) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

BIBLIOGRAPHIE

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
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5. World Health Organisation (1984) Expert Committee on Biological Standards, *Technical Series,* **700:** 19.
6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Thromboplastin L
Anleitung — de

VERWENDUNGSZWECK

Das Thromboplastin L Kit ist für koagulometrische Gerinnungstests vorgesehen.

Die erste standardisierte Prothrombinzeit als Einstufen-Test wurde 1935 von Dr. Armand Quick entwickelt. Mittlerweile ist er der Standard-Screeningtest in der Gerinnung zur Diagnose eines vererbten oder erworbenen Gerinnungsfaktormangels des extrinsischen Systems (Faktor II, V, VII und X)[1,2]. Er wird auch zur Einstellung und Überwachung von oralen Antikoagulanztherapien[3,4] verwendet und kann bei chronischen und akuten Lebererkrankungen zur Beurteilung der Funktionsfähigkeit der Leber bei der Proteinsynthese herangezogen werden.
Thromboplastin L wird aus Kaninchenhirn gewonnen, ähnelt aber mit seinem niedrigen „International Sensitivity Index" (ISI) humaner Blutgerinnungszeit. Der ISI von Thromboplastin L liegt bei ca. 1,1 und ist gegen WHO „International Reference Preparation" kalibriert[5]. Thromboplastin L ist besonders für die Überwachung oraler Antikoagulanztherapien geeignet und, in Verbindung mit dem entsprechenden Faktor-Mangelplasma, bei der Messung von Faktoraktivitäten im extrinsischen System. Gewebethromboplastin ist in Anwesenheit von Calcium-Ionen ein Aktivator, der das extrinsische Gerinnungssystem auslöst. Gibt man eine Mischung von Gewebethromboplastin und Calcium-Ionen zu normalem Citratplasma, wird die Gerinnungskaskade aktiviert und es bildet sich ein Fibringerinnsel. Besteht innerhalb des extrinsischen Systems ein Mangel, verlängert sich, je nach Schwere dieses Mangels, die Zeit bis zur Ausbildung eines Gerinnsels.

WARNHINWEISE UND VORSICHTSMASSNAHMEN

Die in diesem Kit enthaltenen Reagenzien sind ausschließlich für die Verwendung von *in-vitro*-Diagnosen vorgesehen. NICHT VERSCHLUCKEN. Tragen Sie beim Umgang mit sämtlichen Komponenten des Kits geeignete Schutzausrüstung. Beachten Sie gegebenenfalls die Verweise auf entsprechende Gefahren- und Vorbeugeerklärungen in der Produktsicherheitserklärung. Entsorgen Sie die Komponenten gemäß den örtlichen Vorschriften.

ZUSAMMENSETZUNG

Komponente	Inhalt	Beschreibung	Vorbereitung
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Flüssiges Thromboplastin aus Hasenhirn mit Calciumchlorid, Stabilisatoren und Konservierungsstoffen.	Das flüssige, kalzifizierte Thromboplastin ist einsatzbereit. Für die Durchführung von standardmäßigen PT-Analysen ist kein zusätzliches Calcium erforderlich. Der Inhalt der Ampulle muss vor der Verwendung gut gemischt werden (5 Minuten auf dem Walzenmischer).

Jedes Kit enthält eine Gebrauchsanweisung

Jedes Kit enthält chargenspezifischen Referenzwerten

ERFORDERLICHE, ABER NICHT MITGELIEFERTE ARTIKEL

Die folgenden Produkte können in Kombination mit Thromboplastin L verwendet werden:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

LAGERUNG, HALTBARKEIT UND STABILITÄT

Ungeöffnete Reagenzien sind unter den auf Verpackung oder Fläschchen angegebenen Lagerbedingungen bis zum aufgedruckten Verfallsdatum stabil.

Thromboplastin L	Offene Ampullen sind 2 Monate bei $^{+}$2 –$^{+}$8°C, 5 Tage bei $^{+}$15°C (im Sysmex CA-1500) und 6 Stunden bei $^{+}$37°C (im AC-4 mit Reagenzbehälter und Deckel) stabil. Eine Stabilität von 7 Tagen im Schichteinsatz (Sysmex CA-1500) kann erreicht werden. NICHT EINFRIEREN. Große Verklumpungen oder Veränderungen in den Normalwerten können auf eine Verfall des Produkts hinweisen.

PROBENENTNAHME UND VORBEREITUNG

Nur Plastik oder Silikonglas verwenden. Blut (9 Teile) sollte in 3,2% oder 3,8% Natriumcitrat als Antikoagulanz (1 Teil) entnommen werden. 15 Minuten bei 1500 g zentrifugieren und Plasma abpipettieren. Plasma bei $^{+}$18 –$^{+}$24°C lagern. Plasma sollte innerhalb von 4 Stunden verarbeitet oder tief gefroren bei -20°C für 2 Wochen oder -70°C für 6 Monat gelagert werden. Vor dem Testen schnell bei $^{+}$37°C auftauen. Nicht länger als 5 Minuten bei $^{+}$37°C belassen[6].

VORGEHENSWEISE

Um einen korrekten INR zu erhalten wird empfohlen, den laborspezifischen ISI für das Reagenz mit dem verwendeten Testsystem zu bestimmen. Helena Biosciences Europe empfiehlt zu diesem Zweck das Plasma-Kalibrator-Set REF 5519[7,8]. Das sollte mit jeder neuen Reagenzien-Charge durchgeführt werden. Das Helena Biosciences Europe INR Reference Set (REF 5490) dient zur Überprüfung von Verschiebungen im ISI vor Ort, die unter anderem durch Veränderungen der Labortemperatur und nach Wartungsarbeiten an den Geräten festgestellt worden sind.

Manuelle Methode

1. Mischen Sie eine ausreichende Menge von Thromboplastin L an, um die für den Tag geplanten Tests durchzuführen und inkubieren Sie es nicht länger als 4 Stunden bei $^{+}$37°C.
2. 0,1 mL des zu testenden Plasmas bei $^{+}$37°C 2 Minuten vorwärmen.
3. 0,2 mL des frisch zubereiteten Thromboplastin-Reagenz zum Plasma pipettieren, dabei gleichzeitig Stoppuhr drücken.
4. Die Zeit bis zur Gerinnselbildung bis auf 0,1 Sekunden genau stoppen.

Automatisierte Methoden

Siehe die Bedienungsanleitung des entsprechenden Geräts für genaue Anweisungen oder wenden Sie sich an Helena Biosciences Europe für spezielle anwendungstechnische Hinweise.

INTERPRETATION DER ERGEBNISSE

Ergebnisse sollten bis auf 0,1 Sekunden genau gemessen werden und Doppelbestimmungen nicht mehr als 5% abweichen. % TPZ-Werte können ausgehend von der Kalibratorkurve interpoliert werden (% TPZ des TP-Kalibrationsplasmas zu gemessener Gerinnungszeit) und sollten auf doppeltlogarithmischem Millimeterpapier eine gerade Linie ergeben.

INR-Werte können anhand der folgenden Formel berechnet werden: INR = (PT Zeit Patient / Mittelwert normale TPZ)^{ISI}

Für klare Leitlinien zu den Indikationen für und der Versorgung von Patienten unter Warfarin siehe die aktuelle Ausgabe der "Guidelines on oral anticoagulation with warfarin" der British Society for Haematology. Zum Zeitpunkt der Drucklegung ist das die 4. Ausgabe, 2011[9].

EINSCHRÄNKUNGEN

Die Verwendung einer Serienverdünnung von Referenzplasma ist für die %PT-Kurve nicht zu empfehlen, da das zu Diskrepanzen aufgrund von niedrigem Fibrinogen in den Referenzplasma-Verdünnungen führen kann, das nicht den Patientenproben entspricht, die in der Regel normale Fibrinogen-Werte haben. Helena Biosciences Europe empfiehlt zu diesem Zweck das Set 5504R %PT/Direct INR einzusetzen.

QUALITÄTSKONTROLLE

Jedes Labor muss für eine eigene Qualitätskontrolle sorgen. Vor jeder Testreihe mit Patientenproben müssen normale und pathologische Kontrollplasmen getestet werden, um eine zufrieden stellende Geräteleistung und Bedienung zu gewährleisten. Liegen die Kontrollen außerhalb des Normbereichs, sind die Patientenergebnisse nicht zu verwenden.
In Verbindung mit diesem Produkt bietet Helena Biosciences Europe die folgenden Kontrollen an:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seine eigenen Referenzwertbereiche erstellen. Dieses ist besonders für die ISI-Kalibration vor Ort wichtig. Mit der Instrumentenreihe Sysmex liegen die typischen Normwerte zwischen 11,50 - 14,60 Sekunden; 0.930 - 1.160 INR; 79.10 - 112.80 %PT .

LEISTUNGSMERKMALE

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag mit einem Sysmex CA-1500 Gerinnungsgerät ermittelt. Jedes Labor muss seine eigenen Werte ermitteln.

Reproduzierbarkeit

Probe	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Wiederholbarkeit	0,07	0,59	0,24	1,09	0,45	1,11
Bei verschiedenen Analysen	0,10	0,83	0,16	0,75	0,49	1,20
An verschiedenen Tagen	0,04	0,32	0,06	0,27	0,25	0,62
Selbes Gerät/Labor	0,12	1,07	0,29	1,35	0,72	1,75

Störungen

Helena Thromboplastin L ist unempfindlich gegenüber Heparinwerten bis zu 2 Einheiten/mL. Mit einer Störschwelle von 5 % gibt es keine besondere Interferenz durch Hämoglobin bei Konzentrationen von bis zu 10 g/l. Mit einer Störschwelle von 5 % gibt es keine besondere Interferenz durch Bilirubin bei Konzentrationen von bis zu 0,5 g/l bei Thromboplastin L. Lipidinterferenztests zeigen, dass die Lipidmenge die Gerinnungszeit des Reagenz bis 3,7 g/l nicht direkt beeinflusst. Höhere Lipidkonzentrationen verhindern die Gerinnungserkennung.

Methodenvergleich

Thromboplastin L und Thromboplastin LI wurden an 268 Proben angewandt. Dabei wurden die Gerinnungszeit in Sekunden verglichen und die INR-Werte bestimmt. Es ergaben sich folgende Korrelationen:

Thromboplastin L (sekunden) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

LITERATURVERZEICHNIS

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Thromboplastin L
Istruzioni per l'uso

it

SCOPO PREVISTO

III kit Thromboplastin L è concepito per l'esecuzione di dosaggi di emostasi basati sulla presenza di coaguli.

I primo test del tempo di protrombina standardizzato venne messo a punto dal Dr. Armand Quick nel 1935. Attualmente, questo test è diventato il metodo basilare di screening della coagulazione per la diagnosi di deficienze congenite ed acquisite dei fattori di coagulazione dal percorso estrinseco (fattori II, V, VII e X)[1,2]. Questo test viene utilizzato anche per l'induzione e il monitoraggio della terapia anticoagulante orale[3,4] e può essere impiegato per valutare la capacità di sintesi proteica del fegato in disordini epatici cronici o acuti.
Il kit Thromboplastin L è realizzato a partire da cervello di coniglio, ma rassomiglia a BCT umano in termini di basso indice di sensibilità internazionale (ISI). L'ISI del kit Thromboplastin L è approssimativamente pari a 1,1 ed è calibrato rispetto alla preparazione di riferimento internazionale dell'OMS[5]. Il kit Thromboplastin L è particolarmente indicato per il monitoraggio della terapia anticoagulante orale e, in combinazione con plasma carente del fattore appropriato, per la misurazione dell'attività del fattore nel percorso estrinseco. In presenza di ioni di calcio, la tromboplastina tissutale è un attivatore che dà inizio al percorso di coagulazione estrinseco. Quando una miscela di tromboplastina tissutale e di ioni di calcio viene aggiunta a normale plasma citrato, si attiva il meccanismo di coagulazione che porta alla formazione di un coagulo di fibrina. Qualora sussista una deficienza all'interno del percorso estrinseco, il tempo richiesto per la formazione del coagulo risulterà prolungato in funzione della gravità della deficienza.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Tromboplastina liquida di cervello di coniglio contenente cloruro di calcio, stabilizzatori e conservanti.	La tromboplastina calcica liquida è pronta all'uso. Per eseguire dosaggi PT standard non è necessario altro calcio. Il contenuto della fiala deve essere miscelato accuratamente prima dell'uso (5 minuti su un rullo).

Ogni kit contiene un Istruzioni per l'uso.

Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

In combinazione con la Thromboplastin L è possibile utilizzare i seguenti prodotti:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

CONSERVAZIONE, VITA UTILE E STABILITÀ

I reagenti non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sul flacone o sull'etichetta del kit

Thromboplastin L — Le fiale aperte sono stabili per 2 mesi ad una temperatura compresa tra $^{+}$2 e $^{+}$8°C, per 5 giorni a $^{+}$15°C (Sysmex CA-1500 on-board) e per 6 ore a $^{+}$37°C (AC-4 on-board compresi il contenitore del reagente e il tappo). È possibile ottenere una stabilità d'uso di 7 giorni (Sysmex CA-1500).
NON CONGELARE. Ammassi consistenti di particelle o variazioni nei valori previsti possono essere indice di deterioramento del prodotto.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Nel corso dell'intera procedura è necessario utilizzare plastica o vetro siliconizzato. Il sangue (9 parti) deve essere raccolto in sodio citrato al 3,2% o al 3,8% come anticoagulante (1 parte). Separare il plasma in seguito a centrifugazione a 1500 x g per 15 minuti. Il plasma deve essere conservato a $^{+}$18 –$^{+}$24°C. I test devono essere completati entro 4 ore dalla raccolta dei campioni; in alternativa, il plasma può essere conservato congelato a -20°C per 2 settimane o a -70°C per 6 mese. Decongelare rapidamente a $^{+}$37°C prima di eseguire i test. Non conservare a $^{+}$37°C per oltre 5 minuti[6].

PROCEDURA

Per un rilevamento accurato dell'INR si raccomanda di determinare l'ISI specifico del laboratorio per il reagente con il sistema di test in uso. A tale scopo si raccomanda il ISI Calibrant Plasma Set (REF 5519) di Helena Biosciences Europe[7,8]. Questa procedura deve essere eseguita per ogni nuovo lotto di reagente. L'INR Reference Set (REF 5490) di Helena Biosciences Europe deve invece essere utilizzato per rilevare eventuali spostamenti dell'ISI del sistema locale osservati in concomitanza con cambiamenti della temperatura del laboratorio e in seguito a manutenzione dello strumento, tra le altre variazioni locali.

Metodo Manuale

1. Miscelare un quantitativo di Thromboplastin L sufficiente a completare i test previsti per la giornata e incubare a +37°C per un massimo di 4 ore.
2. Preriscaldare 0,1 mL di plasma di prova a $^{+}$37°C per 2 minuti.
3. Aggiungere al plasma 0,2 mL di reagente a base di tromboplastina appena miscelato, azionando contemporaneamente un cronometro.
4. Annotare il tempo di formazione del coagulo con un'approssimazione a 0,1 secondi.

Metodo Automatico

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europe per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

I risultati devono essere indicati con un'approssimazione a 0,1 secondi e le ripetizioni devono corrispondere con una tolleranza del 5%. I valori di %PT possono essere interpolati dal grafico di calibrazione (%PT dei plasmi di calibrazione PT vs. tempo di coagulazione rilevato), che, se tracciato su carta a doppia scala logaritmica, deve apparire sotto forma di linea retta.

I valori di INR possono essere calcolati utilizzando la seguente formula: $INR = (\text{Tempo di PT Paziente} / \text{Tempo di PT normale medio})^{ISI}$

Per una guida chiara sulle indicazioni per la gestione dei pazienti con warfarina fare riferimento a The British Society for Haematology per la loro edizione più aggiornata delle 'Linee guida sull'anticoagulazione orale con warfarina'. Al momento della stampa questa è la quarta edizione del 2011[9].

LIMITAZIONI

Si sconsiglia l'impiego di diluizioni seriali di un plasma di riferimento per la curva %PT, che infatti possono dare luogo a discrepanze dovute al basso livello di fibrinogeno nelle diluizioni del plasma di riferimento, che non compaiono invece nei campioni dei pazienti con livelli di fibrinogeno prevalentemente normali. Helena Biosciences Europe consiglia di utilizzare a questo scopo il kit 5504R %PT/Direct INR.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.
Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALORI DI RIFERIMENTO

Per la sicurezza del paziente, è necessario che il sistema sia monitorato continuamente da un operatore qualificato. Per tale motivo ciascun laboratorio dovrà elaborare i propri range di riferimento. Ciò è particolarmente importante per la calibrazione dell'ISI locale. Con l'impiego della gamma di strumenti Symex, i valori normali che variano tra 11,50 - 14,60 secondi; 0.930 - 1.160 INR; 79.10 - 112.80 %PT sono ritenuti tipici.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione Sysmex CA-1500. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali.

Riproducibilità

Campione	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Ripetibilità	0,07	0,59	0,24	1,09	0,45	1,11
Tra le serie	0,10	0,83	0,16	0,75	0,49	1,20
Tra giorni	0,04	0,32	0,06	0,27	0,25	0,62
All'interno del dispositivo/laboratorio	0,12	1,07	0,29	1,35	0,72	1,75

Interferenze

La Thromboplastin L Helena non è sensibile ai livelli di eparina di oltre 2 U/mL. Utilizzando una soglia di interferenza del 5%, non risulta esserci alcuna significativa interferenza da parte dell'emoglobina a concentrazioni fino a 10 g/l. Utilizzando una soglia di interferenza del 5%, non risulta esserci alcuna significativa interferenza da parte della bilirubina a concentrazioni fino a 0,5 g/l per la Thromboplastin L. I test per le interferenze dei lipidi dimostrano che i livelli dei lipidi non influenzano direttamente il tempo di coagulazione del reagente fino a 3,75 g/l. Concentrazioni lipidiche superiori a questo valore impediscono il rilevamento del coagulo.

Confronto dei metodi

Si è eseguito un confronto su 268 campioni tra il tempo di coagulazione in secondi e i valori INR utilizzando la tromboplastina L e la tromboplastina LI. Si sono ottenute le seguenti correlazioni:

Thromboplastin L (secondi) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

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2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
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Thromboplastin L
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Thromboplastin L es realizar ensayos de hemostasia basados en la coagulación.

La primera prueba estandarizada de la protrombina en una sola etapa fue desarrollada por el Dr. Armand Quick en 1935. Ahora se ha convertido en la prueba de cribado básico de la coagulación para el diagnóstico de deficiencias congénitas y adquiridas de factores de coagulación de la vía extrínseca (factores II, V, VII y X)[1,2]. Se usa también para la inducción y monitorización del tratamiento anticoagulante oral[3,4] y puede usarse para valorar la capacidad de síntesis de proteínas del hígado en trastornos hepáticos crónicos o agudos.
La Thromboplastin L tiene su origen en cerebro de conejo, pero se parece a la BCT humana en su bajo Índice de Sensibilidad Internacional (ISI). El ISI de Thromboplastin L es de aproximadamente 1,1 y se calibra contra el preparado de referencia internacional de la OMS[5]. La prueba de Thromboplastin L está especialmente adaptada a la monitorización del tratamiento anticoagulante oral y, conjuntamente con el plasma deficiente en el factor oportuno, la medición de la actividad de los factores en la vía extrínseca. La tromboplastina tisular, en presencia de iones calcio, es un activador que inicia la vía extrínseca de la coagulación. Cuando se añade una mezcla de tromboplastina tisular e iones calcio al plasma normal citratado, se activa el mecanismo de coagulación, conduciendo a un coágulo de fibrina. Si se produce una deficiencia dentro de la vía extrínseca, el tiempo necesario para la formación de coágulos se prolongará dependiendo de la intensidad de la deficiencia.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*: NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Tromboplastina líquida de cerebro de conejo que contiene cloruro de calcio, estabilizadores y conservantes.	La tromboplastina líquida calcificada está lista para su uso. No es necesario más calcio para realizar pruebas estándar de PT. Los contenidos del vial se deben mezclar bien antes de utilizarlo (5 minutos en el rodillo).

Cada kit contiene instrucciones de uso.

Cada kit contiene valores de referencia específicos insertados del lote.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

Los siguientes productos se puede utilizar junto con la Thromboplastin L:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los reactivos no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit.

Thromboplastin L — Los viales abiertos permanecen estables durante 2 meses a una temperatura de entre $^{+}$2 – $^{+}$8°C, 5 días a una temperatura mayor a $^{+}$15°C (en el Sysmex CA1500), y 6 horas a una temperatura mayor a $^{+}$37°C (en el AC-4, incluido el contenedor del reactivo y el tapón). Se puede conseguir estabilidad multiuso de 7 días (Sysmex CA-1500).
NO CONGELAR. Los grumos grandes de partículas o los cambios en los valores esperados pueden indicar deterioro del producto.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

Debe usarse siempre plástico o vidrio siliconizado. Debe recogerse sangre (9 partes) en el anticoagulante citrato sódico al 3,2% o al 3,8% (1 parte). Separar el plasma después de la centrifugación a 1500 x g durante 15 minutos. El plasma debe conservarse a $^{+}$18 –$^{+}$24°C. Las pruebas deberían terminarse en 4 horas desde la recogida de las muestras o el plasma puede conservarse congelado a -20°C durante 2 semanas o -70°C durante 6 mes. Descongelar rápidamente a $^{+}$37°C antes de realizar la prueba. No conservar a $^{+}$37°C durante más de 5 minutos[6].

PROCEDIMIENTO

Para la comunicación exacta del INR, se recomienda determinar la ISI específica del laboratorio del reactivo con el sistema de prueba en uso. Se recomienda el ISI Calibrant Plasma Set de Helena Biosciences Europe (REF 5519) para este fin[7,8]. Esto debe realizarse para cada nuevo lote de reactivos. Debe usarse el Set de Referencia de INR de Helena Biosciences Europe (REF 5490) para comprobar las desviaciones en el ISI del sistema local que se han observado con cambios en la temperatura del laboratorio y el mantenimiento posinstrumental, entre otras variaciones locales.

Método Manual

1. Mezclar la cantidad suficiente de Thromboplastin L para completar la prueba anticipada para el día e incubar a +37°C durante un período de tiempo no superior a 4 horas.
2. Precaliente 0,1 mL del plasma de prueba a $^{+}$37°C durante 2 minutos.
3. Añada 0,2 mL de reactivo de tromboplastina recién mezclado al plasma mientras pone en marcha simultáneamente un cronómetro.
4. observa el tiempo hasta la formación del coágulo procurando afinar en la décima 0,1 de segundo más próxima.

Método Automatizado

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE LOS RESULTADOS

Los resultados deben comunicarse en los 0,1 segundos más próximos y las pruebas duplicadas deben estar de acuerdo entre sí dentro del 5%. Los valores de %TP pueden interpolarse a partir del gráfico de calibración (%TP de los plasmas de calibración del TP frente al tiempo de coágulo medido) que debe ser una línea recta cuando se representa en un papel de gráficos log-log.

Los valores de INR pueden calcularse usando la siguiente fórmula: $INR = (\text{Tiempo de TP Paciente} / \text{Tiempo de TP normal medio})^{ISI}$

Si necesita una guía clara de indicaciones y tratamiento de pacientes con warfarina, consulte The British Society for Haematology y su última edición de "Guidelines on oral anticoagulation with warfarin" que, en el momento de impresión de este documento, se encuentra en su cuarta edición de 2011[9].

LIMITACIONES

El uso de diluciones seriadas de un plasma de referencia para la curva de %TP no se recomienda, porque puede llevar a discrepancias producidas por el bajo fibrinógeno en las diluciones del plasma de referencia, que no se reflejan en las muestras de pacientes que tienen fundamentalmente niveles normales de fibrinógeno. Helena Biosciences Europe recomienda utilizar el kit 5504R %PT/INR directa a tal fin.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los controles normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.
Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer su propio intervalo normal. Esto es especialmente importante para la calibración local del ISI. Con la serie de instrumentos Sysmex, es frecuente que los valores normales varíen entre 11,50 - 14,60 segundos; 0.930 - 1.160 INR; 79.10 - 112.80 %PT .

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación Sysmex CA-1500. Cada laboratorio debe establecer sus propios datos de rendimiento.

Reproductibilidad

Muestra	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Repetibilidad	0,07	0,59	0,24	1,09	0,45	1,11
Entre series	0,10	0,83	0,16	0,75	0,49	1,20
Entre días	0,04	0,32	0,06	0,27	0,25	0,62
En el dispositivo/laboratorio	0,12	1,07	0,29	1,35	0,72	1,75

Interferencias

Helena Thromboplastin L no detecta niveles de heparina inferiores a 2 U/mL.Con un umbral de interferencia del 5%, no hay interferencias significativas de hemoglobina en concentraciones de hasta 10 g/L. Con un umbral de interferencia del 5%, no hay interferencias significativas de bilirrubina en concentraciones de hasta 0,5 g/L para Thromboplastin L. La interferencia de lípidos demuestra que los niveles de lípidos no afectan directamente al tiempo de coagulación del reactivo hasta 3,75 g/L. Las concentraciones de lípidos superiores evitan detectar la coagulación.

Comparación del método

La comparación del tiempo de coagulación y los valores INR se determinó con tromboplastina L y tromboplastina LI en 268 muestras. Se obtuvieron las siguientes correlaciones:

Thromboplastin L (segundo) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

BIBLIOGRAFÍA

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
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4. Poller L (1986) Laboratory Control of Anticoagulant Therapy, *Sem. Thromb. Haemostasis,* **12:** 13-19.
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6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Тест-система "Жидкий тромбопластин"
инструкция

ru

НАЗНАЧЕНИЕ

Комплект Тест-система "Жидкий тромбопластин" предназначен для выполнения анализов гемостаза на основе кровяного сгустка.

Впервые стандартизированный одностадийный тест для определения протромбинового времени был предложен д-ром Армандом Квиком в 1935г. Сейчас он стал основным скрининговым тестом для диагностики врожденного и приобретенного дефицитов факторов свертывания крови по внешнему пути (факторы II, V, VII и X)[1,2]. Он также используется для мониторинга терапии оральными антикоагулянтами[3,4], а также может применяться и для оценки белок синтетической функции печени при ее острых либо хронических заболеваниях.
Реагент приготовлен из экстракта ткани мозга кролика и по значению своего МИЧ (Международного Индекса Чувствительности) сопоставим со Стандартом Тромбопластина Британии (BCT – British Comparative Thromboplastin). МИЧ Жидкого тромбопластина примерно равен 1.1 и откалиброван относительно международного референса BO3[5]. Жидкий тромбопластин особенно подходит для мониторинга терапии оральными антикоагулянтами и для измерения активности факторов внешнего пути свертывания(вместе с соответствующей фактор-дефицитной плазмой). Тканевый тромбопластин в присутствии йонов кальция является активатором внешнего пути свертывания крови. При добавлении смеси тканевого тромбопластина с кальцием к нормальной цитратной плазме активируется механизм её свертывания, приводящий к образованию фибринового сгустка. Если у пациента имеет место дефицит факторов внешнего пути, то время, необходимое для образования сгустка будет удлиняться прямо пропорционально степени дефицита факторов.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

СОСТАВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Жидкий тромбопластин	2 x 5 мл (Кат.№ 5265HL) 8 x 5 мл (Кат.№ 5265L) 10 x 10 мл (Кат.№ 5267L)	Тромбопластин-кальциевая суспензию реагента из экстракта ткани мозга кролика, раствора хлорида кальция и стабилизаторов	Жидкий кальцинированный тромбопластин, готовый для использования. Для проведения теста ПВ дополнительный кальций не требуется. Содержимое флакона перемешать до использования (5 мин. на роллере)

Каждый набор содержит инструкцию по применению.

Вкладыш с указанием референсных значений к различным анализаторам и методам исследования, характерным для данного лота.

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Продукция ниже, которая может использоваться вместе с Тест-системой «Тромбопластин»:

Кат.№ 5519	Калибратор МИЧ
Кат.№ 5490	Контроль на МНО

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Невскрытые флаконы с реагентами хранятся до истечения срока годности в условиях, указанных на этикетке.

Жидкий тромбопластин	Вскрытые флаконы годны к применению в течение 2 месяцев при температуре хранения 2-8°C, 5 дней при 15°C (на борту Sysmex CA-1500) и 6 часов при 37°C (на борту AC-4, используя контейнер для реагентов с крышкой). Стабильность реагента на борту Sysmex CA-1500 - 7 дней. НЕ ЗАМОРАЖИВАТЬ! Признаки ухудшения качества реагента: большое скопление частиц или отличия от ожидаемых значений могут означать ухудшение свойств реактива.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Для работы следует использовать только пластиковые или силиконированные стеклянные пробирки. Кровь забирается в пробирку с цитратным антикоагулянтом (3,2% или 3,8% цитрат натрия) в соотношении 9 + 1. После центрифугирования при 1500 g, в течение 15 минут (использование других параметров должно проверяться лабораторией), полученную плазму необходимо отделить от форменных элементов крови. Плазму следует хранить при температуре $^{+}$18 –$^{+}$24°C. Тестирование должно быть проведено в течение 4 часов после забора образцов, либо плазму можно однократно заморозить и хранить при температуре -20°C в течение 2 недель или при -70°C в течение 6 месяцев. Перед проведением исследования плазму следует быстро разморозить при $^{+}$37°C. Не держать плазму при $^{+}$37°C более 5 минут[6].

ПРОЦЕДУРА

Для установления более точного МНО рекомендуется определить специфическое для лаборатории значение МИЧ (так называемый «локальный» МИЧ) для жидкого тромбопластина. Helena Biosciences Europe рекомендует для этих целей применять Калибратор МИЧ (Кат.№ REF 5519)[7,8]. Подобная процедура должна быть проведена для каждой новой партии реагентов. Контроль на МНО (Кат.№ REF 5490) используется для контроля изменения в «локальном» МИЧ, так как его значение может незначительно варьировать в зависимости от используемых приборов, а также изменений температуры в лаборатории и других локальных факторов.

Ручной Метод

1. Взять необходимое количество жидкого тромбопластина, необходимое для проведения тестирования в течение дня и инкубировать при 370С (но не более 4 часов).
2. Прогреть 0,1 мл тестируемой плазмы при $^{+}$37°C в течение 2 минут.
3. Добавить 0,2 мл свежеприготовленной рабочей смеси реагентов к плазме и немедленно включить таймер.
4. Заметить время, необходимое для образования сгустка с точностью до 0,1сек.

Автоматизированный Метод

Для проведения тестирования на автоматических коагулометрах, необходимо обратиться к руководству пользователя и к соответствующей адаптации, которые доступны у официальных дистрибьюторов и компании Хелена.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Результаты должны быть представлены с точностью до 0,1 сек и разница в повторах не должна превышать 5%. Значение %ПВ можно определить по калибровочному графику (график зависимости %ПВ от измеренного времени), который должен быть строго линейным в билогарифмических координатах при построении графика на миллиметровке с логарифмическим масштабом на обеих осях.

МНО может быть вычислено по формуле: $МНО = \{\text{ПВ (пациента)} / \text{среднее ПВ (норма)}\}^{МИЧ}$

Для более подробной информации по мониторингу пациентов на Варфарине обратитесь к рекомендациям Британского Общества по Гематологии - «Рекомендации по антикоагулянтной терапии варфарином», 4-е издание 2011г. на время печати этого документа[9].

ОГРАНИЧЕНИЯ

Для получения графика зависимости (%ПТ) от времени свертывания не рекомендуется использовать серии разведений референсной плазмы, поскольку это может привести к неточности, вызванной низким содержанием фибриногена в больших разведениях референсной плазмы, что не соответствует образцам пациентов, имеющих, в основном, нормальный уровень фибриногена. Компания Хелена рекомендует использовать калибратор кат. номер 5504R для %ПВ, и прямого определения МНО.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными.
Компания Хелена рекомендует следующие контрольные материалы:

Кат.№ 5186	Контроль качества, норма
Кат.№ 5187	Контроль качества, умеренно выраженная патология
Кат.№ 5183	Контроль качества, высокая патология
Кат.№ 5490	Контроль на МНО

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и анализаторов. В связи с этим каждая лаборатория должна определить свою собственную область нормальных значений. Это крайне важно для установки локального МИЧ тромбопластина. Диапазон нормальных значений пациентов 11,50 - 14,60 сек.; 0.930 - 1.160 INR; 79.10 - 112.80 %PT с использованием коагулометров Sysmex.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики. При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость

Образец	Контроль качества, норма		Контроль качества, умеренно выраженная патология		Контроль качества, высокая патология	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Воспроизводимость	0,07	0,59	0,24	1,09	0,45	1,11
в пределах аналитической серии	0,10	0,83	0,16	0,75	0,49	1,20
между разными аналитическими сериями	0,04	0,32	0,06	0,27	0,25	0,62
между партиями/лабораториями	0,12	1,07	0,29	1,35	0,72	1,75

Тест-система "Жидкий тромбопластин" не чувствителен к гепарину в концентрации до 2 Ед/мл. Используя 5% допустимое отклонение, реагент не чувствителен к гемоглобину в концентрации до 10 г/Л. Используя 5% допустимое отклонение, реагент не чувствителен к билирубину в концентрации до 0.5 г/Л. Не обнаружено чувствительности к уровню липидов до 3.75 г/Л оказывающих воздействие на время свёртываемости. Концентрации липидов выше этого уровня предотвратит обнаружение сгустка.

Сравнение со стандартами:
Сравнение значений МНО 268 образцов, определённых с помощью Тест-системы "Тромбопластин" и Тест-системы "Жидкий тромбопластин" дало следующие корреляционные соотношения:

Жидкий Тромбопластин (сек) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Жидкий Тромбопластин (МНО) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

ЛИТЕРАТУРА

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
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5. World Health Organisation (1984) Expert Committee on Biological Standards, *Technical Series,* **700:** 19.
6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

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Coagulation Control Plasmas

REF 5186 Routine Control N
REF 5187 Routine Control A
REF 5183 Routine Control SA
REF 5482 Routine Coagulation Control Set

CE IVD

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HL-2-0482P 2016/01 (16)

Coagulation Control Plasmas
Instructions for use — en

INTENDED PURPOSE
The Coagulation Control Plasmas kit is intended for use as a quality control material.

Routine Control N, Routine Control A and Routine Control SA are for use as normal, moderately prolonged and markedly prolonged controls for PT and aPTT assays. They are also assayed for Fibrinogen, TCT and ATIII, and are prepared from normal human plasma.

WARNINGS AND PRECAUTIONS
The reagents contained in this kit are for *in vitro* diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all kit components. Refer to the product safety declaration for the link to appropriate hazard and precautionary statements where applicable. Dispose of components in accordance with local regulations.

Blood products have been screened and found negative (unless otherwise stated on the kit box or vial) for the presence of:
Hepatitis B Antigen (HbsAg)
HIV 1 antibody HIV 2 antibody
HCV antibody
However they should be handled with the same precautions as a human patient sample.

COMPOSITION

REF	Component	Content	Description
5186	Routine Control - N	10 x 1 mL	Prepared from pooled normal plasma.
5187	Routine Control - A	10 x 1 mL	Prepared from adsorbed human plasma.
5183	Routine Control - SA	10 x 1 mL	Prepared from adsorbed human plasma.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Each kit contains instructions for use.
Each kit contains lot specific reference values insert.

Each vial contains 1 mL of buffered, lyophilised human plasma.
Preparation: Reconstitute each vial of the appropriate control with 1 mL of distilled or deionised water. Swirl gently. Allow to stand for 10 minutes for complete dissolution and mix well before use.

ITEMS REQUIRED BUT NOT PROVIDED
Coagulation Control Plasmas may be used when performing tests on any mechanical or photo-optical coagulation instrument in conjunction with all suitable, commercial reagents.

STORAGE, SHELF-LIFE AND STABILITY
Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label. The reconstituted controls are stable for 8 hours when kept at +2 –+8°C or 4 weeks at -20°C when flash frozen. Keep covered.

SAMPLE COLLECTION AND PREPARATION
Not applicable.

PROCEDURE
Each control should be treated in the same manner as the unknown specimen in accordance with the instructions outlined in each particular test protocol.

INTERPRETATION OF RESULTS
Routine Control N should give values within the laboratory normal range for PT, aPTT and fibrinogen assays. Routine Control A and Routine Control SA have been standardised to give prolonged and markedly prolonged PT and aPTT times respectively. Lot and instrument specific expected values are provided with each pack of controls.

LIMITATIONS
The results obtained with Coagulation Control Plasmas depend on several factors strongly associated with instrumentation, types of reagents, deficient substrates and laboratory to laboratory variations[1,2,3]. Each laboratory should establish an expected range for the particular instrument-reagent system.

QUALITY CONTROL
Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.

REFERENCE VALUES
Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own reference ranges.

PERFORMANCE CHARACTERISTICS
The following performance characteristics have been determined by Helena Biosciences Europe or their representatives using an opto-mechanical coagulation instrument. Each laboratory should establish its own performance data.

Reproducibility

		Intra-assay precision	
Sample	*n*	*aPTT CV (%)*	*PT CV (%)*
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

BIBLIOGRAPHY
1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Plasmas de contrôle de coagulation
Fiche technique — fr

UTILISATION
Le kit Coagulation Control Plasmas est destiné à être utilisé comme produit de contrôle qualité.

Les contrôles Routine Control N, Routine Control A et Routine Control SA servent de témoins normal, modérément prolongé et nettement prolongé dans les déterminations du TP et du TCA. Le fibrinogène, la TCT et l'ATIII ont été dosés et ils sont préparés à partir de plasma humain normal.

AVERTISSEMENTS ET PRÉCAUTIONS
Les réactifs du kit sont à usage diagnostique *in vitro* uniquement – NE PAS INGÉRER. Porter un équipement de protection individuelle approprié lors de la manipulation de tous les composants du kit. Consulter la fiche de données de sécurité du produit pour obtenir le lien vers les phrases de risque et les conseils de prudence le cas échéant. Éliminer les composants conformément aux églementations locales.

Un dépistage des produits sanguins a été réalisé et a donné un résultat négatif (sauf indication contraire sur la boîte du kit ou sur le flacon) quant à la présence de :
Antigène de l'hépatite B (AgHBs)
Anticorps anti-VIH 1
Anticorps anti-VIH 2
Anticorps anti-VHC
Cependant, ils doivent être manipulés avec les mêmes précautions que celles prises pour les échantillons patients humains.

COMPOSITION

REF	Composant	Contient	Description
5186	Routine Control - N	10 x 1 mL	Préparé à partir d'un pool de plasma normal.
5187	Routine Control - A	10 x 1 mL	Préparés à partir de plasma humain adsorbé.
5183	Routine Control - SA	10 x 1 mL	Préparés à partir de plasma humain adsorbé.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Chaque kit contient une fiche technique.
Chaque kit contient valeurs de référence spécifiques du lot.

Chaque flacon contient 1 mL de plasma humain tamponné lyophilisé.
Préparation: Reconstituer chaque flacon du contrôle approprié avec 1 mL d'eau distillée ou désionisée. Agiter doucement. Attendre 10 minutes jusqu'à dissolution totale et bien mélanger avant d'utiliser.

MATÉRIEL NÉCESSAIRE NON FOURNI
Le Coagulation Control Plasmas peut être utilisé dans les analyses réalisées sur des instruments de coagulation mécanique ou photo-optique avec les réactifs appropriés vendus dans le commerce.

CONSERVATION, DURÉE DE VIE UTILE ET STABILITÉ
Les flacons non ouverts sont stables jusqu'à la date de péremption indiquée s'ils sont conservés dans les conditions indiquées sur l'étiquette du kit ou du flacon. Une fois reconstitués, les contrôles sont stables 8 heures entre +2 –+8°C ou 4 semaines à -20 °C en cas de congélation instantanée. Couvrir le produit.

PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS
Non applicable.

PROCÉDURE
Chaque contrôle doit être traité de la même manière que l'échantillon à analyser en observant les instructions de chaque protocole spécifique.

INTERPRÉTATION DES RÉSULTATS
Le Routine Control N doit donner des valeurs se situant dans la plage normale du laboratoire pour le TP, le TCA et le fibrinogène. Le Routine Control A et le Routine Control SA ont été standardisés pour donner des temps TP et TCA prolongés et très prolongés respectivement. Les valeurs prévues spécifiques du lot et de l'instrument sont fournies avec chaque kit de contrôles.

LIMITES
Les résultats obtenus avec le Coagulation Control Plasmas dépendent de plusieurs facteurs fortement corrélés avec l'instrument, les types de réactifs, les substrats carencés et les variations inter-laboratoires[1,2,3]. Le laboratoire doit déterminer une plage prévue pour chaque système instrument-réactif.

CONTRÔLE QUALITÉ
Chaque laboratoire doit établir un programme de contrôle qualité. Les plasmas de contrôle, normaux et anormaux, doivent être testés avant chaque lot d'échantillons patients afin de s'assurer que l'instrument et l'opérateur offrent des performances satisfaisantes. Si les contrôles ne donnent pas les résultats prévus, les résultats du patient doivent être considérés comme non valables.

VALEURS DE RÉFÉRENCE
Les valeurs de référence peuvent varier d'un laboratoire à l'autre suivant les techniques et les systèmes utilisés. C'est pour cette raison qu'il appartient à chaque laboratoire de déterminer ses propres plages de référence.

CARACTÉRISTIQUES DE PERFORMANCES
Helena Biosciences Europe ou ses mandataires ont déterminé les caractéristiques de performance suivantes en utilisant un instrument de coagulation opto-mécanique. Chaque laboratoire doit établir ses propres données de performance.

Reproductibilité

		Précision intra-série	
Échantillon	*n*	*TCA CV (%)*	*TP CV (%)*
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

BIBLIOGRAPHIE
1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Kontrollplasma für die Gerinnung
Anleitung — de

VERWENDUNGSZWECK
Das Coagulation Control Plasmas-Kit ist für die Qualitätskontrolle vorgesehen.

Routine Control N, Routine Control A und Routine Control SA sind als normale, mäßig verzögerte und stark verzögerte Kontrollen für PT und aPTT Tests geeignet. Sie sind auch auf Fibrinogen, TZ und AT-III getestet und werden aus normalem Humanplasma hergestellt.

WARNHINWEISE UND VORSICHTSMASSNAHMEN
Die in diesem Kit enthaltenen Reagenzien sind ausschließlich für die Verwendung von *in-vitro*-Diagnosen vorgesehen. NICHT VERSCHLUCKEN. Tragen Sie beim Umgang mit sämtlichen Komponenten des Kits geeignete Schutzausrüstung. Beachten Sie gegebenenfalls die Verweise auf entsprechende Gefahren- und Vorbeugeerklärungen in der Produktsicherheitserklärung. Entsorgen Sie die Komponenten gemäß den örtlichen Vorschriften.

Die Blutprodukte wurden untersucht und sind für folgende Gene ohne Befund (soweit nicht anderweitig auf der Verpackung oder den Ampullen angegeben):
Hepatitis-B-Antikörper (HbsAg)
HIV-Antikörper 1
HIV-Antikörper 2
HCV-Antikörper
Sie sind jedoch mit den gleichen Vorkehrungen zu behandeln wie Proben von menschlichen Patienten.

ZUSAMMENSETZUNG

REF	Komponente	Inhalt	Beschreibung
5186	Routine Control - N	10 x 1 mL	Aus gepooltem Humanplasma hergestellt.
5187	Routine Control - A	10 x 1 mL	Adsorbiertem Humanplasma hergestellt.
5183	Routine Control - SA	10 x 1 mL	Adsorbiertem Humanplasma hergestellt.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Jedes Kit enthält eine Gebrauchsanweisung.
Jedes Kit enthält chargenspezifischen Referenzwerten.

Jedes Fläschchen enthält 1 mL gepuffertes, lyophilisiertes Humanplasma.
Vorbereitung: Jedes Fläschchen Kontrollplasma mit 1 mL destilliertem oder entionisiertem Wasser rekonstituieren. Leicht schwenken. Zum vollständigen Auflösen 10 Minuten stehen lassen und vor Gebrauch gut mischen.

ERFORDERLICHE, ABER NICHT MITGELIEFERTE ARTIKEL
Coagulation Control Plasmas kann in Verbindung mit allen entsprechenden kommerziellen Reagenzien bei der Durchführung von Tests an mechanischen oder lichtoptischen Koagulometern verwendet werden.

LAGERUNG, HALTBARKEIT UND STABILITÄT
Ungeöffnete Fläschchen sind unter den auf Verpackung oder Fläschchen angegebenen Lagerbedingungen bis zum aufgedruckten Verfallsdatum stabil. Rekonstituierte Kontrollen sind bei +2 —+8°C 4 Wochen stabil bzw. 4 Wochen bei -20 °C, wenn schockgefroren. Verschlossen aufbewahren.

PROBENENTNAHME UND VORBEREITUNG
Entfällt.

VORGEHENSWEISE
Jede Kontrolle sollte gemäß den Anleitungen der einzelnen Testprotokolle wie unbekannte Probe behandelt werden.

INTERPRETATION DER ERGEBNISSE
Routine Control N sollte für PT, aPTT und Fibrinogen Tests Werte im Normalbereich ergeben. Routine Control A und Routine Control SA wurden standardisiert, um verlängerte bzw. stark verlängerte PT und aPTT Zeiten zu ergeben. Chargen und Geräte spezifische Normalwerte sind in jeder Packung mit Kontrollen enthalten.

EINSCHRÄNKUNGEN
Die mit Coagulation Control Plasmas erzielten Resultate hängen von mehreren Faktoren ab, die stark mit dem Gerät, den verwendeten Reagenzien, mangelnden Substraten und Unterschieden zwischen den Labors in Verbindung stehen[1,2,3]. Jedes Labor sollte daher für jedes Geräte-Reagenzien-System einen eigenen Normalwertebereich erstellen.

QUALITÄTSKONTROLLE
Jedes Labor muss für eine eigene Qualitätskontrolle sorgen. Normale und pathologische Kontrollplasmen müssen vor jeder Testreihe mit Patientenproben getestet werden, um eine zufrieden stellende Gerätleistung und Bedienung zu gewährleisten. Liegen die Kontrollen außerhalb des Normbereichs, sind die Patientenergebnisse nicht zu verwenden.

REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seine eigenen Referenzwertbereiche erstellen.

LEISTUNGSMERKMALE

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag mit einem optomechanischen Gerinnungsgerät ermittelt. Jede Labor muss seine eigenen Werte ermitteln.

Reproduzierbarkeit

		Intra-assay-Präzision	
Probe	***n***	***aPTT CV (%)***	***PT CV (%)***
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

LITERATURVERZEICHNIS

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Plasmi di controllo della coagulazione
Istruzioni per l'uso

it

SCOPO PREVISTO

Il kit Coagulation Control Plasmas è concepito per l'uso come materiale di controllo qualità.

Routine Control N, Routine Control A e Routine Control SA sono destinati ad essere utilizzati come controlli normali, moderatamente prolungati e marcatamente prolungati per i dosaggi di PT e aPTT. Essi vengono dosati anche per fibrinogeno, TCT e ATIII e sono preparati con plasma umano normale.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

I prodotti ematici sono stati sottoposti a screening e trovati negativi (salvo diversa indicazione sulla confezione del kit o sulla fiala) per la presenza di:
Antigene dell'epatite B (HbsAg)
Anticorpo HIV 1
Anticorpo HIV 2
Anticorpo HCV
Questi prodotti devono tuttavia essere manipolati con le stesse misure precauzionali adottate per un campione paziente umano.

COMPOSIZIONE

REF	Componente	Contiene	Descrizione
5186	Routine Control - N	10 x 1 mL	Preparato con un pool di plasma normale.
5187	Routine Control - A	10 x 1 mL	Preparati con plasma umano adsorbito.
5183	Routine Control - SA	10 x 1 mL	Preparati con plasma umano adsorbito.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Ogni kit contiene un Istruzioni per l'uso.

Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

Ogni flacone contiene 1 mL di plasma umano tamponato liofilizzato.

Preparazione: Ricostituire ogni flacone di controllo appropriato con 1 mL di acqua distillata o deionizzata. Agitare delicatamente. Attendere 10 minuti per consentire al prodotto di sciogliersi completamente e miscelare bene prima dell'uso.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

Il Coagulation Control Plasmas può essere utilizzato durante l'esecuzione di test su qualsiasi strumento di coagulazione meccanico o foto-ottico in combinazione con tutti i reagenti idonei disponibili in commercio.

CONSERVAZIONE, VITA UTILE E STABILITÀ

Ogni riferimento a nomi e dati utilizzati negli esempi è casuale, se non specificato diversamente. I controlli ricostituiti sono stabili per 8 ore se conservati a $^{+}2$ — $^{+}8$°C oppure 4 settimane a -20°C se congelato molto velocemente. Mantenere i prodotti coperti.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Non applicabile.

PROCEDURA

Ogni controllo deve essere trattato seguendo la stessa procedura adottata per il campione non noto, conformemente alle istruzioni riportate in ciascun protocollo di test specifico.

INTERPRETAZIONE DEI RISULTATI

Routine Control N deve fornire valori compresi nel range normale di laboratorio per i dosaggi di PT, aPTT e fibrinogeno. Routine Control A e Routine Control SA sono stati standardizzati per fornire, rispettivamente, tempi di PT e aPTT prolungati e marcatamente prolungati. I valori previsti specifici per il lotto e lo strumento vengono forniti con ciascuna confezione di controlli.

LIMITAZIONI

I risultati ottenuti con il Coagulation Control Plasmas dipendono da innumerevoli fattori, strettamente legati alla strumentazione, ai tipi di reagenti, a substrati carenti e alle variazioni dovute ai singoli laboratori[1,2,3]. Ogni laboratorio dovrà definire un range di previsione per il sistema strumento-reagente specificamente utilizzato.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.

VALORI DI RIFERIMENTO

Per la sicurezza del paziente, è necessario che il sistema sia monitorato continuamente da un operatore qualificato. Per tale motivo ciascun laboratorio dovrà elaborare i propri range di riferimento.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione opto-meccanico. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali.

Riproducibilità

		Precisione intra-dosaggio	
Campione	***n***	***aPTT CV (%)***	***PT CV (%)***
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

BIBLIOGRAFIA

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Plasmas de control de la coagulación
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Coagulation Control Plasmas es como material de control de calidad.

Routine Control N, Routine Control A y Routine Control SA se usan como controles normal, moderadamente prolongado y notablemente prolongado para las valoraciones de TP y TTPa. También se valoran para fibrinógeno, TCT y ATIII y se elaboran a partir de plasma humano normal.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*: NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

La sangre se ha sometido a pruebas que han resultado negativas (a menos que se indique lo contrario en la caja del kit o en el vial) de la presencia de:
Antígeno de la hepatitis B (HbsAg)
Anticuerpos del VIH 1
Anticuerpos del VIH 2
Anticuerpos del VHC
Sin embargo, deben manipularse con las mismas precauciones que una muestra de un paciente.

COMPOSICIÓN

REF	Componente	Contiene	Descripción
5186	Routine Control - N	10 x 1 mL	Elabora a partir de plasma normal de reserva.
5187	Routine Control - A	10 x 1 mL	Elaboran a partir de plasma humano adsorbido.
5183	Routine Control - SA	10 x 1 mL	Elaboran a partir de plasma humano adsorbido.
5482	Routine Coagulation Control Set:		
	Routine Control - N	4 x 1 mL	
	Routine Control - A	3 x 1 mL	
	Routine Control - SA	3 x 1 mL	

Cada kit contiene instrucciones de uso.

Cada kit contiene valores de referencia específicos insertados del lote.

Cada vial contiene 1 mL de plasma humano tamponado, liofilizado.

Preparación: Reconstituya cada vial del control adecuado con 1 mL de agua destilada o desionizada. Agite suavemente. Deje que repose durante 10 minutos para que la disolución sea completa y mezcle bien antes de su uso.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

El Coagulation Control Plasmas puede usarse cuando se realizan pruebas con cualquier instrumento de coagulación mecánica o foto-óptica junto con todos los reactivos adecuados, comerciales.

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los viales no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit. Los controles reconstituidos son estables durante 8 horas cuando se conservan a $^{+}2$ — $^{+}8$°C o durante 4 semanas a -20°C cuando se conserva con congelación instantánea. Manténgase cubierto.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

No aplicable.

PROCEDIMIENTO

Cada control debe tratarse de la misma forma que la muestra desconocida, de acuerdo con las instrucciones indicadas en cada protocolo de prueba concreto.

INTERPRETACIÓN DE LOS RESULTADOS

Routine Control N debe dar valores dentro del intervalo normal de laboratorio para TP, TTPa y valoraciones de fibrinógeno. El Routine Control A y el Routine Control SA han sido estandarizados para dar tiempos de TP y TTPa prolongados y notablemente prolongados, respectivamente. Se aportan los valores esperados específicos de lote y de instrumento con cada paquete de controles.

LIMITACIONES

Los resultados obtenidos con Coagulation Control Plasmas dependen de varios factores fuertemente asociados a la instrumentación, los tipos de reactivos, sustratos deficientes y variaciones entre laboratorios[1,2,3]. Cada laboratorio debe establecer un intervalo esperado para el sistema instrumento-reactivo concreto.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los plasmas de control normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer sus propios intervalos de referencia.

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación opto-mecánico. Cada laboratorio debe establecer sus propios datos de rendimiento.

Riproducibilità

		Precisión intra-ensayo	
Muestra	***n***	***TTPa CV (%)***	***TP CV (%)***
Routine Control N	5	2.83	1.01
Routine Control A	5	2.76	1.71
Routine Control SA	5	1.72	1.03

BIBLIOGRAFÍA

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

КОНТРОЛЬНЫЕ ПЛАЗМЫ
инструкция

ru

НАЗНАЧЕНИЕ

Комплект Coagulation Control Plasmas предназначен для использования в качестве материала для контроля качества.

Контрольные плазмы: «Контроль качества, норма», «Контроль качества, высокая патология», «Контроль качества, умеренно выраженная патология» – контроли качества с нормальным, умеренно увеличенным и значительно увеличенным активированным парциальным тромбопластиновым временем (АПТВ/АЧТВ) и протромбиновым временем (ПВ). Их также можно использовать для определения количества фибриногена, тромбинового времени (ТВ) и антитромбина III (АТ-III). Контроли приготовлены из человеческой плазмы практически здоровых людей.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

Препараты крови были подвергнуты скринингу и показали отрицательный результат (если на коробке, в которую упакован комплект или на пробирке не указано иное) на:
Антиген к гепатиту B (HbsAg)
Антитела к ВИЧ 1
Антитела к ВИЧ 2
Антитела к вирусу гепатита C (HCV)
Тем не менее с ними следует обращаться, соблюдая те же меры предосторожности, что и при обращении с образцом, полученным от человека.

СОСТАВ

Кат. №	Компоненты	Состав набора	Описание
5186	Контроль качества, норма	10 x 1 мл	приготовлен из пула нормальной плазмы.
5187	Контроль качества, умеренно выраженная патология	10 x 1 мл	приготовлен из адсорбированной плазмы.
5183	Контроль качества, высокая патология	10 x 1 мл	приготовлен из адсорбированной плазмы.
5482	Контроль коагуляции, уровень П1:		
	Контроль качества, норма	4 x 1 мл	
	Контроль качества, умеренно выраженная патология	3 x 1 мл	
	Контроль качества, высокая патология	3 x 1 мл	

Каждый набор содержит инструкцию по применению.

Паспорт с референсными значениями (допустимых/контрольных пределов).

Каждый флакон содержит 1.0 мл лиофилизированной плазмы человека.

Подготовка: Разведите соответствующую контрольную плазму добавлением во флакон 1.0 мл дистиллированной или деионизированной воды. Осторожно перемешайте и оставьте при комнатной температуре в течение 10 минут. Перед использованием флакон с разведенной плазмой переворачивайте (без встряхивания).

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Контрольные плазмы могут быть использованы с анализаторами, имеющими различный метод детекции (механический, оптический и т.д.) в сочетании с реагентами различных производителей.

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Невскрытые флаконы с лиофилизированной плазмой хранятся до истечения срока годности в условиях, указанных на этикетке. Разведенная контрольная плазма в закрытом флаконе может храниться при $^{+}2$ — $^{+}8$°C или 4 недель при -20°C в случае мгновенной заморозки. в течение 8 часов.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Не относится.

ПРОЦЕДУРА

Каждый образец контрольной плазмы должен анализироваться так же, как образец плазмы больного, в соответствии с инструкциями к используемому реагенту и прибору.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

«Контроль качества, норма», должен показывать значения в пределах нормального диапазона используемого в лаборатории для ПВ, АПТВ и определения концентрации фибриногена. «Контроль качества, умеренно выраженная патология» и «Контроль качества, высокая патология», были стандартизированы, таким образом, чтобы показывать соответственно умеренно или выраженное увеличение АПТВ и ПВ. Номер партии и допустимые/контрольные пределы для различных коагулометров поставляются с каждым набором контролей.

ОГРАНИЧЕНИЯ

Референсные значения могут варьировать между лабораториями в зависимости от используемых реагентов, методов, коагулометров и других факторов[1,2,3]. По этой причине каждая лаборатория должна установить свои собственные нормативные параметры метода.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными.

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и коагулометров. По этой причине каждая лаборатория должна установить свои собственные значения.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики.
При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость

		в пределах аналитической серии	
Контрольная плазма	***Кол-во образцов***	***CV (%) АПТВ***	**CV (%) ПВ**
Контроль качества, норма	5	2.83	1.01
Контроль качества, умеренно выраженная патология	5	2.76	1.71
Контроль качества, высокая патология	5	1.72	1.03

ЛИТЕРАТУРА

1. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
2. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
3. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

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Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

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Calibration Plasma

REF 5185

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HL-2-0424P 2016/01 (14)

Calibration Plasma
Instructions for use — en

INTENDED PURPOSE

The Calibration Plasma kit is intended for use as a calibration material.

Calibration Plasma may be used as a reference plasma when assaying for Factors II, V, VII, VIII, IX, X[1], XI, XII[2], fibrinogen[3], von Willebrand Factor, antigenic and functional Protein C and Protein S (total and free), as well as the chromogenic assays including Antithrombin (AT) III, Protein C, Factor VIII and Plasminogen. Calibration Plasma is used in factor assays and other testing in the same manner as a fresh plasma pool. Factor II, VII, VIII, IX and X values and the chromogenic Factor VIII, AT III and Protein C values are traceable to World Health Organisation standards to ensure the utmost credibility in values stated[4]. The reference plasma should be used to gauge internal factors in each laboratory's system. The reference plasma should not be used to determine normal ranges since normals vary from population to population.

WARNINGS AND PRECAUTIONS

The reagents contained in this kit are for *in vitro* diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all kit components. Refer to the product safety declaration for the link to appropriate hazard and precautionary statements where applicable. Dispose of components in accordance with local regulations.

Blood products have been screened and found negative (unless otherwise stated on the kit box or vial) for the presence of:
Hepatitis B Antigen (HbsAg)
HIV 1 antibody HIV 2 antibody
HCV antibody
However they should be handled with the same precautions as a human patient sample.

COMPOSITION

Component	Content	Description	Preparation
Calibration Plasma	10 x 1 mL	Calibration Plasma is prepared from a frozen pool of citrated plasma from healthy donors and is buffered and lyophilised to ensure stability of all plasma constituents[5].	Reconstitute with 1 mL of distilled or deionised water. Swirl gently. Allow product 20 minutes for complete dissolution.

Each kit contains instructions for use.

Each kit contains a lot specific reference values insert.

ITEMS REQUIRED BUT NOT PROVIDED

Calibration Plasma may be used when performing tests on any mechanical or photo-optical coagulation instrument in conjunction with all suitable, commercial reagents.

STORAGE, SHELF-LIFE AND STABILITY

Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label. Values for Factor VIII, von Willebrand factor and ristocetin co-factor are stable for 2 hours at $^{+}2$ –$^{+}8$°C. All other factors are stable for 4 hours at $^{+}2$ –$^{+}8$°C. The unreconstituted Calibration Plasma must appear as a light yellow, dry plug. If any unusual conditions are noted, the customer should notify Helena Biosciences Europe, before using.

SAMPLE COLLECTION AND PREPARATION

Not applicable.

PROCEDURE

Refer to the appropriate instrument Operator Manual for detailed instructions or contact Helena Biosciences Europe for instrument-specific application guides.

INTERPRETATION OF RESULTS

The assayed percent activities of the various coagulation factors should be taken from the "Reference Value" column when Calibration Plasma is used to determine the laboratory's standard curves. Ensure the lot number printed on this assay sheet is the same as that on the vial of Calibration Plasma to be used.

LIMITATIONS

The results obtained with Calibration Plasma depend on several factors strongly associated with instrumentation, types of reagents, deficient substrates and laboratory to laboratory variations[6,7,8]. Each laboratory should establish an expected range for the particular instrument-reagent system.

QUALITY CONTROL

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
Helena Biosciences Europe supplies the following controls available for use with this product:

REF 5301 Speciality Assayed Control N

REF 5302 Speciality Assayed Control A

REFERENCE VALUES

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own normal range.

PERFORMANCE CHARACTERISTICS

The following performance characteristics have been determined by Helena Biosciences Europe or their representatives using an opto-mechanical coagulation instrument. Each laboratory should establish its own performance data.

Reproducibility

Inter-batch precision

Parameter	*n*	*Mean*	*CV (%)*
Fibrinogen (g/L)	5	3.0	3.6
Factor IX (%)	5	124.7	1.9
Protein S (%)	5	98.5	2.8

BIBLIOGRAPHY

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP,* **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
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5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
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7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Calibration Plasma
Fiche technique — fr

UTILISATION

Le kit Calibration Plasma est destiné à être utilisé comme produit d'étalonnage.

Le Calibration Plasma peut être utilisé comme plasma de référence lors du dosage des facteurs II, V, VII, VIII, IX, X[1], XI, XII[2], du fibrinogène[3], du facteur von Willebrand, de la protéine C antigénique et fonctionnelle et de la protéine S (total et libre) ainsi que des dosages chromogéniques dont celui de l'antithrombine III, de la protéine C, du facteur VIII et du plasminogène. Le Calibration Plasma sert à doser les facteurs et à réaliser d'autres analyses de la même façon que s'il s'agissait d'un pool de plasma frais. Le taux des facteurs II, VII, VIII, IX et X ainsi que le dosage chromogénique du facteur VIII, de l'AT-III et de la protéine C sont en conformité avec les normes de l'Organisation mondiale de la santé afin de garantir la véracité des valeurs indiquées[4]. Le plasma de référence doit être utilisé pour étalonner les facteurs dans chaque laboratoire. Il ne sert pas déterminer une plage de valeurs normales car celles-ci varient d'une population à l'autre.

AVERTISSEMENTS ET PRÉCAUTIONS

Les réactifs du kit sont à usage diagnostique *in vitro* uniquement – NE PAS INGÉRER. Porter un équipement de protection individuelle approprié lors de la manipulation de tous les composants du kit. Consulter la fiche de données de sécurité du produit pour obtenir le lien vers les phrases de risque et les conseils de prudence le cas échéant. Éliminer les composants conformément aux églementations locales.

Un dépistage des produits sanguins a été réalisé et a donné un résultat négatif (sauf indication contraire sur la boîte du kit ou sur le flacon) quant à la présence de :
Antigène de l'hépatite B (AgHBs)
Anticorps anti-VIH 1
Anticorps anti-VIH 2
Anticorps anti-VHC
Cependant, ils doivent être manipulés avec les mêmes précautions que celles prises pour les échantillons patients humains.

COMPOSITION

Composant	Contient	Description	Préparation
Calibration Plasma	10 x 1 mL	Le Calibration Plasma est préparé à partir d'un pool de plasma citraté congelé provenant de donneurs sains, puis est tamponné et lyophilisé afin de garantir la stabilité de tous les constituants du plasma[5].	Reconstituer en ajoutant 1,0 mL d'eau distillée ou désionisée. Agiter doucement. Attendre 20 minutes que le produit se dissolve complètement.

Chaque kit contient une fiche technique.

Chaque kit contient valeurs de référence spécifiques du lot.

MATÉRIEL NÉCESSAIRE NON FOURNI

Le Calibration Plasma peut être utilisé dans les analyses réalisées sur des instruments de coagulation mécanique ou photo-optique avec les réactifs appropriés vendus dans le commerce.

CONSERVATION, DURÉE DE VIE UTILE ET STABILITÉ

Les flacons non ouverts sont stables jusqu'à la date de péremption indiquée s'ils sont conservés dans les conditions indiquées sur l'étiquette du kit ou du flacon. Les valeurs du facteur VIII, du facteur von Willebrand et du cofacteur de la ristocétine sont stables 2 heures entre $^{+}2$ –$^{+}8$°C. Tous les autres facteurs sont stables 4 heures entre $^{+}2$ –$^{+}8$°C. Le Calibration Plasma non reconstitué est un lyophilisat sec de couleur jaune clair. S'il présente des caractéristiques inhabituelles, le client doit prévenir Helena Biosciences Europe avant de l'utiliser.

PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS

Non applicable.

PROCÉDURE

Consulter le manuel d'utilisation de l'instrument approprié pour obtenir des instructions détaillées ou contacter Helena Biosciences Europe pour obtenir des notes d'application spécifiques à l'instrument.

INTERPRÉTATION DES RÉSULTATS

Les pourcentages d'activité dosée des différents facteurs de coagulation doivent être pris dans la colonne « Valeur de référence » lorsque le Calibration Plasma est utilisé pour déterminer les courbes d'étalonnage du laboratoire. S'assurer que le numéro de lot imprimé sur cette fiche de dosage coïncide avec celui du flacon de Calibration Plasma à utiliser.

LIMITES

Les résultats obtenus avec le Calibration Plasma dépendent de plusieurs facteurs fortement corrélés avec l'instrument, les types de réactifs, les substrats carencés et les variations inter-laboratoires[6,7,8]. Le laboratoire doit déterminer une plage prévue pour chaque système instrument-réactif.

CONTRÔLE QUALITÉ

Chaque laboratoire doit établir un programme de contrôle qualité. Les plasmas de contrôle, normaux et anormaux, doivent être testés avant chaque lot d'échantillons patients afin de s'assurer que l'instrument et l'opérateur offrent des performances satisfaisantes. Si les contrôles ne donnent pas les résultats prévus, les résultats du patient doivent être considérés comme non valables.

Helena Biosciences Europe distribue les contrôles suivants à utiliser avec ce produit:
REF 5301 Speciality Assayed Control N
REF 5302 Speciality Assayed Control A

VALEURS DE RÉFÉRENCE

Les valeurs de référence peuvent varier d'un laboratoire à l'autre suivant les techniques et les systèmes utilisés. C'est pour cette raison qu'il appartient à chaque laboratoire de déterminer sa propre plage normale.

CARACTÉRISTIQUES DE PERFORMANCES

Helena Biosciences Europe ou ses mandataires ont déterminé les caractéristiques de performance suivantes en utilisant un instrument de coagulation opto-mécanique.

Reproductibilite

Précision inter-lots

Paramètre	*n*	*Moyenne*	*CV (%)*
Fibrinogène (g/L)	5	3.0	3.6
Facteur IX (%)	5	124.7	1.9
Protéine S (%)	5	98.5	2.8

BIBLIOGRAPHIE

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP,* **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP,* **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Calibration Plasma
Anleitung — de

VERWENDUNGSZWECK

Das Calibration Plasma-Kit ist für die Kalibration vorgesehen.

Calibration Plasma kann als Referenzplasma bei der Untersuchung auf Faktor II, V, VII, VIII, IX, X[1], XI, XII[2], Fibrinogen[3], von Willebrand Faktor, Antigen und Funktion von Protein C und Protein S (gesamt und frei), sowie für Chromogen-Tests einschließlich Antithrombin III, Protein C, Faktor VIII und Plasminogen verwendet werden. Calibration Plasma wird für Faktor-Bestimmungen und andere Tests wie frisches Pool-Plasma verwendet. Faktor II, VII, VIII, IX und X Werte und die chromogenen Faktor VIII, AT-III und Protein C Werte sind entsprechend den Standards der World Health Organisation nachweisbar, um den angegebenen Werten die größtmögliche Plausibilität zu verleihen[4]. Das Referenzplasma sollte dazu verwendet werden, um die internen Faktoren für das jeweilige Laborsystem einzustellen. Es sollte weiterhin dazu verwendet werden, Normalbereiche festzulegen, da sie von der jeweiligen Population abhängig sind.

WARNHINWEISE UND VORSICHTSMASSNAHMEN

Die in diesem Kit enthaltenen Reagenzien sind ausschließlich für die Verwendung von *in-vitro*-Diagnosen vorgesehen. NICHT VERSCHLUCKEN. Tragen Sie beim Umgang mit sämtlichen Komponenten des Kits geeignete Schutzausrüstung. Beachten Sie gegebenenfalls die Verweise auf entsprechende Gefahren- und Vorbeugeerklärungen in der Produktsicherheitserklärung. Entsorgen Sie die Komponenten gemäß den örtlichen Vorschriften.

Die Blutprodukte wurden untersucht und sind für folgende Gene ohne Befund (soweit nicht anderweitig auf der Verpackung oder den Ampullen angegeben):
Hepatitis-B-Antikörper (HbsAg)
HIV-Antikörper 1
HIV-Antikörper 2
HCV-Antikörper
Sie sind jedoch mit den gleichen Vorkehrungen zu behandeln wie Proben von menschlichen Patienten.

ZUSAMMENSETZUNG

Komponente	Inhalt	Beschreibung	Vorbereitung
Calibration Plasma	10 x 1 mL	Calibration Plasma wird aus einem tief gefrorenen Pool Citratplasma von gesunden Spendern hergestellt und ist zur Gewährleistung der Stabilität aller Plasmabestandteile gepuffert und lyophilisiert[5].	Mit 1,0 mL destilliertem oder entionisiertem Wasser rekonstituieren. Leicht schwenken. Produkt 20 Minuten vollständig auflösen lassen.

Jedes Kit enthält eine Gebrauchsanweisung.

Jedes Kit enthält chargenspezifischen Referenzwerten.

ERFORDERLICHE, ABER NICHT MITGELIEFERTE ARTIKEL

Calibration Plasma kann in Verbindung mit allen entsprechenden kommerziellen Reagenzien bei der Durchführung von Tests an mechanischen oder lichtoptischen Koagulometern verwendet werden.

LAGERUNG, HALTBARKEIT UND STABILITÄT

Ungeöffnete Fläschchen sind unter den auf Verpackung oder Fläschchen angegebenen Lagerbedingungen bis zum aufgedruckten Verfallsdatum stabil. Werte für Faktor VIII, von Willebrand Faktor und Ristocetin Co-Faktor sind bei $^{+}2$ –$^{+}8$°C Stunden stabil. Alle weiteren Faktoren sind bei $^{+}2$ –$^{+}8$°C Stunden stabil. Nicht rekonstituiertes Calibration Plasma muss als hellgelber, trockner Pfropf erscheinen. Bei einem ungewöhnlichen Erscheinungsbild sollte der Kunde vor Gebrauch Helena Biosciences Europe davon in Kenntnis setzen.

PROBENENTNAHME UND VORBEREITUNG

Entfällt.

VORGEHENSWEISE

Siehe die Bedienungsanleitung des entsprechenden Geräts für genaue Anweisungen oder wenden Sie sich an Helena Biosciences Europe für spezielle anwendungstechnische Hinweise.

INTERPRETATION DER ERGEBNISSE

Die getesteten, prozentualen Aktivitäten der verschiedenen Gerinnungsfaktoren sollten aus der Tabelle „Referenzwerte" für die Erstellung einer laboreigenen Standardkurve mit Calibration Plasma entnommen werden. Darauf achten, dass die Chargen-Nummer auf dem Beipackzettel mit der auf dem verwendeten Calibration Plasma-Fläschchen übereinstimmt.

EINSCHRÄNKUNGEN

Die mit Calibration Plasma erzielten Resultate hängen von mehreren Faktoren ab, die stark mit dem Gerät, den verwendeten Reagenzien, mangelnden Substraten und Unterschieden zwischen den Labors in Verbindung stehen[6,7,8]. Jedes Labor sollte daher für jedes Geräte-Reagenzien-System einen eigenen Normalwertebereich erstellen.

QUALITÄTSKONTROLLE

Jedes Labor muss für eine eigene Qualitätskontrolle sorgen. Normale und pathologische Kontrollplasmen müssen vor jeder Testreihe mit Patientenproben getestet werden, um eine zufrieden stellende Gerätleistung und Bedienung zu gewährleisten. Liegen die Kontrollen außerhalb des Normbereichs, sind die Patientenergebnisse nicht zu verwenden.

In Verbindung mit diesem Produkt bietet Helena Biosciences Europe die folgenden Kontrollen an:
REF 5301 Speciality Assayed Control N
REF 5302 Speciality Assayed Control A

REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seinen eigenen Normalwertbereich erstellen.

LEISTUNGSMERKMALE

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag mit einem optomechanischen Gerinnungsgerät ermittelt.

Reproduzierbarkeit

Inter-batch-Präzision

Parameter	*n*	*Mittelwert*	*CV (%)*
Fibrinogen (g/L)	5	3.0	3.6
Faktor IX (%)	5	124.7	1.9
Protein S (%)	5	98.5	2.8

LITERATURVERZEICHNIS

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP,* **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP,* **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Calibration Plasma
Istruzioni per l'uso

it

SCOPO PREVISTO

Il kit Calibration Plasma è concepito per l'uso come materiale di calibrazione.

Il Calibration Plasma può essere utilizzato come plasma di riferimento per il dosaggio dei fattori II, V, VII, VIII, IX, X[1], XI e XII[2], del fibrinogeno[3], del fattore di von Willebrand, della proteina C e della proteina S (totale e libera) antigeniche e funzionali, nonché per i dosaggi cromogenici, compresi l'antitrombina III, la proteina C, il fattore VIII e il plasminogeno. Il Calibration Plasma viene utilizzato nei dosaggi dei fattori e in altri test seguendo la stessa procedura adottata per un pool di plasma fresco. I valori dei fattori II, VII, VIII, IX e X e i valori cromogenici del fattore VIII, dell'AT-III e della proteina C sono riconducibili agli standard dell'Organizzazione Mondiale della Sanità, a garanzia della massima attendibilità dei valori dichiarati[4]. Il plasma di riferimento deve essere utilizzato per valutare i fattori interni adottati nel sistema di ogni singolo laboratorio. Il plasma di riferimento non deve essere utilizzato per determinare i range normali, in quanto i valori normali variano da una popolazione all'altra.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

I prodotti ematici sono stati sottoposti a screening e trovati negativi (salvo diversa indicazione sulla confezione del kit o sulla fiala) per la presenza di:
Antigene dell'epatite B (HbsAg)
Anticorpo HIV 1
Anticorpo HIV 2
Anticorpo HCV
Questi prodotti devono tuttavia essere manipolati con le stesse misure precauzionali adottate per un campione paziente umano.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
Calibration Plasma	10 x 1 mL	Il Calibration Plasma viene preparato utilizzando un pool congelato di plasma citrato proveniente da donatori sani e quindi viene tamponato e liofilizzato, per garantire la stabilità di tutti i costituenti plasmatici[5].	Ricostituire con 1,0 mL di acqua distillata o deionizzata. Agitare delicatamente. Attendere 20 minuti per consentire al prodotto di sciogliersi completamente.

Ogni kit contiene un Istruzioni per l'uso.

Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

Il Calibration Plasma può essere utilizzato durante l'esecuzione di test su qualsiasi strumento di coagulazione meccanico o foto-ottico in combinazione con tutti i reagenti idonei disponibili in commercio.

CONSERVAZIONE, VITA UTILE E STABILITÀ

I flaconi non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sul flacone o sull'etichetta del kit. I valori relativi al fattore VIII, al fattore di von Willebrand e al cofattore ristocetina sono stabili per 2 ore a $^{+}2$ –$^{+}8$°C. Tutti gli altri fattori sono stabili per 4 ore a $^{+}2$ –$^{+}8$°C. Il Calibration Plasma non ricostituito deve apparire come un tappo asciutto di colore giallo pallido. Qualora si osservassero condizioni insolite, si raccomanda al cliente di notificarle a Helena Biosciences Europe prima dell'uso.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Non applicabile.

PROCEDURA

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europe per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

Quando si utilizza il Calibration Plasma per delineare le curve standard di laboratorio, le percentuali di attività determinate per i vari fattori di coagulazione devono essere ricavate dalla colonna "Valore di riferimento". Assicurarsi che il numero di lotto stampato sul foglio del dosaggio corrisponda a quello riportato sul flacone di Calibration Plasma da utilizzare.

LIMITAZIONI

I risultati ottenuti con il Calibration Plasma dipendono da innumerevoli fattori, strettamente legati alla strumentazione, ai tipi di reagenti, a substrati carenti e alle variazioni dovute ai singoli laboratori[6,7,8]. Ogni laboratorio dovrà definire un range di previsione per il sistema strumento-reagente specificamente utilizzato.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.

Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:
REF 5301 Speciality Assayed Control N
REF 5302 Speciality Assayed Control A

VALORI DI RIFERIMENTO

I valori di riferimento possono variare da un laboratorio all'altro in funzione delle tecniche e dei sistemi in uso. Per tale motivo ciascun laboratorio dovrà elaborare un proprio range normale.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione opto-meccanico.

Riproducibilità

Precisione tra i lotti

Parametro	*n*	*Media*	*CV (%)*
Fibrinogeno (g/L)	5	3.0	3.6
Fattore IX (%)	5	124.7	1.9
Proteina S (%)	5	98.5	2.8

BIBLIOGRAFIA

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP,* **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP,* **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

Calibration Plasma
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Calibration Plasma es como material de calibración.

El Calibration Plasma puede usarse como plasma de referencia cuando se valoran los factores II, V, VII, VIII, IX, X[1], XI, XII[2], fibrinógeno[3], factor de von Willebrand, proteína C antigénica y funcional y proteína S (total y libre), así como las valoraciones cromógenas como antitrombina III, proteína C, factor VIII y plasminógeno. Calibration Plasma se usa en valoraciones de factores y en otras pruebas de la misma forma que una reserva de plasma fresco. Los valores de los factores II, VII, VIII, IX y X y los valores cromogénicos de factor VIII, AT-III y proteína C se pueden referenciar a los estándares de Organización Mundial de la Salud para asegurar la máxima credibilidad en los valores indicados[4]. Debe usarse el plasma de referencia para calibrar factores internos en el sistema de cada laboratorio. No debe usarse el plasma de referencia para determinar los intervalos normales, porque los normales varían de una población a otra.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*: NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

La sangre se ha sometido a pruebas que han resultado negativas (a menos que se indique lo contrario en la caja del kit o en el vial) de la presencia de:

Antígeno de la hepatitis B (HbsAg)

Anticuerpos del VIH 1

Anticuerpos del VIH 2

Anticuerpos del VHC

Sin embargo, deben manipularse con las mismas precauciones que una muestra de un paciente.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
Calibration Plasma	10 x 1 mL	El Calibration Plasma se elabora a partir de una reserva congelada de plasma citratado de donantes sanos y está tamponado y liofilizado para asegurar la estabilidad de todos los constituyentes del plasma[5].	Reconstituya con 1,0 mL de agua destilada o desionizada. Agite suavemente. Espere 20 minutos para que el producto se disuelva completamente.

Cada kit contiene instrucciones de uso.

Cada kit contiene valores de referencia específicos insertados del lote.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

El Calibration Plasma puede usarse cuando se realizan pruebas con cualquier instrumento de coagulación mecánica o foto-óptica junto con todos los reactivos adecuados, comerciales.

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los viales no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en la etiqueta del vial o el kit. Los valores para el factor VIII, el factor de von Willebrand factor y el cofactor de ristocetina son estables durante 2 horas a $^{+}2$ –$^{+}8$°C. Todos los demás factores son estables durante 4 horas a $^{+}2$ –$^{+}8$°C. El Calibration Plasma no reconstituido debe aparecer como un taco seco, de color amarillo claro. Si se nota alguna condición inusual, el usuario debe notificárselo a Helena Biosciences Europe antes de usarlo.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

No aplicable.

PROCEDIMIENTO

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE LOS RESULTADOS

Las actividades porcentuales valoradas de los diversos factores de coagulación deben tomarse de la columna "Valor de Referencia" cuando se usa el Calibration Plasma para determinar las curvas estándar de laboratorio. Compruebe que el número de lote impreso en esta hoja de valoración es el mismo que en el vial de Calibration Plasma a usar.

LIMITACIONES

Los resultados obtenidos con Calibration Plasma dependen de varios factores fuertemente asociados a la instrumentación, los tipos de reactivos, sustratos deficientes y variaciones entre laboratorios[6,7,8]. Cada laboratorio debe establecer un intervalo esperado para el sistema instrumento-reactivo concreto.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los plasmas de control normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.

Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:
REF 5301 Speciality Assayed Control N
REF 5302 Speciality Assayed Control A

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y los sistemas usados. Por esta razón, cada laboratorio debe establecer su propio intervalo normal.

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación opto-mecánico.

Reproductibilidad

Precisión inter-lote

Parámetro	*n*	*Media*	*CV (%)*
Fibrinógeno (g/L)	5	3.0	3.6
Factor IX (%)	5	124.7	1.9
Proteína S (%)	5	98.5	2.8

BIBLIOGRAFÍA

1. Babson AL and Flanagen ML (1975) Quantitative One Stage Assays for Factors V and X, *AJCP,* **64:** 817-819.
2. Hardisty RM *et al.* (1962) A One Stage Factor VIII Assay and Its Use on Venous and Capillary Plasma. *Thrombosis et Diathesis Haemorrhagica*, **7:**215-229.
3. Morse EE *et al.* (1971) Automated Fibrinogen Determination, *AJCP,* **55:**671-676.
4. Elodi S *et al* (1978) Some Sources of Error in the One-Stage Assay of Factor VIII, *Haemostasis*, **7:**1-9.
5. Thelin M (1968) Preparation and Standardization of a Stable AHF Plasma, *Thrombosis et Diathesis Haemorrhagica*, **19:**423.
6. Kirkwood TBL *et al.* (1977) Identification of Sources of Variation in Factor VIII Assay, *British Journal of Haematology,* **37:**559-568.
7. Goldenfarb MD (1971) Reproducibility in Coagulation Assays, *AJCP,* **55:**561-564.
8. Palkuti HA and Longberry JR (1973) A Precision Study of Coagulation Factor Assay Techniques, *AJCP,* **59:**231-235.

УНИВЕРСАЛЬНЫЙ КАЛИБРАТОР
инструкция

ru

НАЗНАЧЕНИЕ

Комплект «Универсальный калибратор» предназначен для использования в качестве материала для калибровки.

«Универсальный калибратор» может использоваться как референсная плазма, для определения факторов II, V, VII, VIII, IX, X[1], XI, XII[2], фибриногена[3], фактора Виллебрандта, антигена и функциональной активности Протеина С и Протеина S (общего и свободного), так же «Универсальный калибратор» можно использовать и для хромогенных тестов, включая Антитромбин III, Протеин С, фактор VIII и Плазминоген. «Универсальный калибратор» используется при калибровке тестов для определения II, VII, VIII, IX и X факторов, а также при калибровке хромогенных тестов: VIII фактора, Антитромбина - III и Протеина С. Уровень значений сопоставим с рекомендациями ВОЗ[4]. Использование референсной плазмы нивелирует влияние внешних факторов на результаты анализа. Референсная плазма не должна использоваться для определения нормального диапазона значений, так как значения нормы варьируют в зависимости от биологических особенностей популяции практически здоровых людей.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

Препараты крови были подвергнуты скринингу и показали отрицательный результат (если на коробке, в которую упакован комплект или на пробирке не указано иное) на:
Антиген к гепатиту В (HbsAg)
Антитела к ВИЧ 1
Антитела к ВИЧ 2
Антитела к вирусу гепатита С (HCV)
Тем не менее с ними следует обращаться, соблюдая те же меры предосторожности, что и при обращении с образцом, полученным от человека.

СОСТАВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Плазма калибратор	10 x 1 мл	приготовлен из объединенной цитратной плазмы, полученной от практически здоровых доноров. Плазма заморожена и лиофилизирована, чтобы гарантировать стабильность всех плазменных элементов[5].	Разведите соответствующую контрольную плазму добавлением во флакон 1.0 мл дистиллированной или деионизированной воды. Осторожно перемешайте и оставьте при комнатной температуре в течение 20 минут. Перед использованием флакон с разведенной плазмой переворачивайте (без встряхивания).

Каждый набор содержит инструкцию по применению.

Паспорт с референсными значениями.

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Контрольные плазмы могут быть использованы с анализаторами, имеющими различный метод детекции (механический, оптический и т.д.) в сочетании с реагентами различных производителей.

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Невскрытые флаконы с лиофилизированной плазмой хранятся до истечения срока годности в условиях, указанных на этикетке. Разведенная плазма в закрытом флаконе может храниться при $^{+}2$ –$^{+}8$°C в течение 4 часов. Значения для VIII фактора, фактор Виллебрандта и КоФактор ристоцетина устойчивы в течение 2 часов при $^{+}2$ –$^{+}8$°C. Неразведенный калибратор должен выглядеть, как светло-желтый сухой плотный лиофилизат. При появлении необычных признаков продукта, до использования обратитесь в компанию Хелена.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Не относится.

ПРОЦЕДУРА

«Универсальный калибратор» может использоваться, для выполнения тестов на любом механическом или оптическом коагулометре в наборе с любыми подходящими реактивами. Адаптации реагентов к различным приборам доступны по запросу у официальных дистрибьюторов и компании Хелена.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Значение процента активности различных факторов свертывания должна быть взята из колонки "референсные значения", когда вы используете «Универсальный калибратор», чтобы определить стандартные лабораторные кривые. Убедитесь, что номер партии, напечатанный в паспорте, совпадает с номером указанным на используемом Вами флаконе калибратора.

ОГРАНИЧЕНИЯ

Референсные значения могут варьировать между лабораториями в зависимости от используемых реагентов, методов, коагулометров и других факторов[6,7,8]. По этой причине каждая лаборатория должна установить свои собственные нормативные параметры метода.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными. Компания Хелена рекомендует следующие контрольные материалы:
Кат. № 5301 Контроль качества специальные тесты, норма
Кат. № 5302 Контроль качества специальные тесты, патология

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и коагулометров. По этой причине каждая лаборатория должна установить свои собственные значения.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики.
При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость

в пределах аналитической серии

Тест	*n*	*Среднее*	*CV (%)*
Фибриноген (г/Л)	5	3.0	3.6
Фактор IX (%)	5	124.7	1.9
Протеин S (%)	5	98.5	2.8

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Declaration of Conformity

HL-7-0136DC DOI 2015/07 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5185	Calibration Plasma	55995

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 28 Jul 2015

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Declaration of Conformity

HL-7-DC-0814 Rev. 1

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

I, the undersigned, declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 24 Nov 2020

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HL-2-P-1787 Rev. 8

APTT Si L Minus
Instructions for use — en

INTENDED PURPOSE

The APTT Si L Minus kit is intended for carrying out clot based haemostasis assays.

For use in the determination of activated partial thromboplastin times (aPTT), and related coagulation procedures using phospholipid extract and a near-collodial particle activator. The test system can be used on manual, semi-automated and automated methods. From its origins through the work of Langdell and coworkers[1], and later modified by Proctor and Rapaport[2], the aPTT is used to detect disorders in the intrinsic coagulation system, which involves coagulation factors VIII, IX, XI, XII, prekallikrein, and high molecular weight kininogen. The aPTT is also used in assays which quantitate these factors and is routinely used for presurgical screening and monitoring of heparin therapy[3]. Commercially available reagents typically use one of three activators: kaolin, silica, or ellagic acid. In the basic screening test, the aPTT indirectly measures the formation of thrombin by its action on fibrinogen forming the fibrin clot. In the test, citrated test plasma is mixed with aPTT reagent for a specified period of time (typically 5 minutes) at +37°C followed by the addition of pre-warmed (+37°C) calcium chloride (0.025 M). Timing is begun from the time of addition of calcium chloride. The time required for clot formation is the aPTT. Clot detection can be by mechanical, manual (tilt tube), or photo-optical measurement.

WARNINGS AND PRECAUTIONS

The reagents contained in this kit are for *in vitro* diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all kit components. Refer to the product safety declaration for the link to appropriate hazard and precautionary statements where applicable. Dispose of components in accordance with local regulations.

COMPOSITION

Component	Content	Description	Preparation
APTT Si L Minus	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Reagent contains a near colloidal particle activator (magnesium-aluminium-silicate) for optimum sensitivity to factor deficiencies and to heparin. The reagent also contains phospholipids with buffer and stabilisers.	Bring to room temperature prior to use. Mix well by swirling or inversion prior to use.
Calcium Chloride: 0.025M	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	The reagent is a 0.025 M solution of calcium chloride.	The reagent is ready for use as packaged.
Each kit contains instructions for use.			

ITEMS REQUIRED BUT NOT PROVIDED

Any high quality electro-mechanical or photo-optical coagulation instrument designed for performing activated partial thromboplastin times may be used.

STORAGE, SHELF-LIFE AND STABILITY

Unopened reagents are stable until the given expiry date when stored under conditions indicated on the vial or kit label. Store at +2° – +8°C. DO NOT FREEZE. Stable for 30 days after opening. Avoid prolonged heating.

SAMPLE COLLECTION AND PREPARATION

Plastic or siliconised glass should be used throughout. Blood (9 parts) should be collected into 3.2% or 3.8% sodium citrate anticoagulant (1 part). Separate plasma after centrifugation at 1500 x g for 15 minutes. Plasma should be kept at +2° – +8°C or +18 – +24°C. Testing should be completed within 4 hours of sample collection, or plasma can be stored frozen at -20°C for 2 weeks or -70°C for 6 months. Thaw quickly at +37°C prior to testing. Do not keep at +37°C for more than 5 minutes. This will minimise the neutralisation of the lupus inhibitor[4]. Erroneous results may be caused by contamination with tissue fluids or stasis. Avoid agitation, air bubbles or foaming. For the effects of commonly administered drugs, refer to Young, *et al.*[5].

PROCEDURE

Manual Method

1. Prewarm well mixed APTT Si L Minus and 0.025 M Calcium Chloride to +37°C.
2. Prewarm 0.1 mL test plasma in duplicate to +37°C for 2 minutes.
3. Forcibly add 0.1 mL prewarmed APTT Si L Minus to plasma and start timer. Incubate for exactly 5 minutes at +37°C.
4. Add 0.1 mL prewarmed 0.025 M Calcium Chloride.
5. Note time for clot formation. Report result as aPTT time (seconds).

Automated Method

Refer to the appropriate instrument operator manual for detailed instructions or contact Helena Biosciences Europe for instrument specific application notes.

INTERPRETATION OF RESULTS

The results of the aPTT test should be reported to the nearest 1/10 of a second. The normal range (usually X ± 2 standard deviations) for each individual laboratory should be established. Results greater than the upper limits of the normal range should be considered abnormal and follow-up testing should be performed. Any aPTT values less than the lower limits of the normal range should be repeated on a new blood sample. Short aPTT values may be seen in association with *in vivo* thrombosis (e.g. deep vein thrombosis and disseminated intravascular coagulation).

Heparin monitoring

When monitoring heparin therapy, it is important to construct an *in vitro* reference curve which reflects the average heparin response, since individual patients respond differently to heparin. In general, one can consider the therapeutic range for heparin to be 0.2 to 0.5 units/mL[3,6].
The following precautions should be considered when monitoring heparin therapy:

1. Time of collection is important, since heparin has an *in vivo* half-life of only 1.5 hours[7].
2. Release of platelet factor 4 (heparin neutralising factor) caused by platelet aggregation or damage during collection, should be avoided. Careful blood collection, proper centrifugation and prompt removal of the platelet poor plasma from the cells will help minimise the release of platelet factor 4.
3. Baseline data on each patient's aPTT should be established before therapy, to determine the respective patient aPTT as it relates to the normal range established by the laboratory.
4. Different clot detection systems (mechanical, photo-optical, etc.) show variable sensitivities to heparin. The same test system should be used when monitoring heparinised patients.
5. Heparin response curves should be reestablished when lot numbers of reagent change and at periodic intervals with the same lot number.
6. The curve should also be constructed using the same heparin employed in therapy, to eliminate variables connected with heparins from different sources (e.g. porcine mucosa or bovine lung).

LIMITATIONS

Expected values for the aPTT test will vary from one laboratory to another, depending on the technique used. The method of clot detection, temperature, pH, collection technique, type of anticoagulant and time and method of specimen storage are all very important. Plasma sample collection and storage conditions should be standardised and carefully controlled. Unexpected results should be confirmed by additional tests. Platelet fragments present in a specimen may cause the release of phospholipids, and thus the neutralisation of any lupus inhibitor present in the specimen. The use of specimens with small plasma volumes should be avoided due to possible physiological pH changes. Testing could be affected by several drugs[5]. An increase in the aPTT results may be caused by the administration of diphenylhydantoin, heparin, warfarin and radiographic agents[5,8]. Decreased aPTT values may be seen during the use of oral contraceptives, or male estrogen therapy[9,10]. Thus, laboratories should establish their own expected values for patients and well defined performance standards for the control.

QUALITY CONTROL

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
Helena Biosciences Europe supplies the following controls available for use with this product:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A

REFERENCE VALUES

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own reference ranges.

PERFORMANCE CHARACTERISTICS

The following performance characteristics have been determined by Helena Biosciences Europe or their representatives using a photo-optical coagulation instrument. Each laboratory should establish its own performance data.

Reproducibility

	Intra-assay precision			Inter-assay precision		
Sample	*n*	*Clot formation (seconds)*	*CV (%)*	*n*	*Clot formation (seconds)*	*CV (%)*
Routine Control N	10	33.0	0.36	100	32.9	2.41
Routine Control SA	10	77.9	0.31	100	78.3	0.77

% Factor	Factor VIII (seconds)	Factor IX (seconds)	Factor XI (seconds)
<1	85.7	70.9	92.4
10	45.9	44.4	50.7
40	34.2	33.9	34.4
100	28.8	28.8	28.8

Heparin (IU/mL)	Clot formation (seconds)
0	29.9
0.2	70.0
0.4	174.0

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APTT Si L Minus
Fiche technique — fr

UTILISATION

Le kit APTT Si L Minus est destiné à la réalisation des analyses de l'hémostase basées sur la formation de caillots.

Utilisé dans la détermination du temps de céphaline activé (TCA), et pour des méthodes de coagulation connexes en utilisant des extraits de le phospholipide additionnés à particules semi-colloïdales comme activateur. Il est possible d'utiliser le système d'analyse avec des méthodes manuelles, semi-automatisées ou automatisées. Dès le début, avec les travaux de Langdell et de ses associés[1], plus tard modifiés par Proctor et Rapaport[2], le TCA est utilisé pour détecter des troubles de la voie intrinsèque de la coagulation, qui implique les facteurs de coagulation VIII, IX, XI, XII, la prékallicréine et le kininogène de haut poids moléculaire. Le TCA est aussi utilisé pour déterminer ces facteurs et est couramment utilisé dans les analyses préopératoires et dans la surveillance de l'héparinothérapie[3]. Les réactifs disponibles sur le marché utilisent en général l'un de ces trois activateurs: kaolin, silice ou acide ellagique. Dans le test de base, le TCA mesure de façon indirecte la formation de thrombine par son action sur le fibrinogène aboutissant à la formation d'un caillot fibrineux. Dans la détermination, le plasma citraté à analyser est mélangé avec le réactif TCA pendant une durée concrète (en général 5 minutes) à +37°C, puis du chlorure de calcium (0,025 M) préchauffé à +37°C est ajouté. Le chronométrage commence au moment de l'ajout du chlorure de calcium. Le temps nécessaire à la formation du caillot est le TCA. Il est possible de détecter la coagulation par une technique mécanique, manuelle (tube incliné) ou avec un instrument photo-optique.

AVERTISSEMENTS ET PRÉCAUTIONS

Les réactifs du kit sont à usage diagnostique *in vitro* uniquement – NE PAS INGÉRER. Porter un équipement de protection individuelle approprié lors de la manipulation de tous les composants du kit. Consulter la fiche de données de sécurité du produit pour obtenir le lien vers les phrases de risque et les conseils de prudence le cas échéant. Éliminer les composants conformément aux réglementations locales.

COMPOSITION

Composant	Contient	Description	Préparation
APTT Si L Minus	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Contient un activateur à particules semi-colloïdales (magnésium-aluminiumsilicate) pour une sensibilité optimale aux déficits de facteurs et à l'héparine. Le réactif contient aussi le phospholipide avec le tampon et les agents de stabilisation.	Ramenez-le à température ambiante avant de l'utiliser. Mélangez bien en remuant ou en renversant avant d'utiliser.
Calcium Chloride: 0.025M	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Le réactif est une solution de chlorure de calcium à 0,025 M.	Le réactif est prêt à l'emploi.
Chaque kit contient une fiche technique.			

MATÉRIEL NÉCESSAIRE NON FOURNI

Il est possible d'utiliser un instrument de coagulation électromécanique ou photo-optique de haute qualité conçu pour déterminer le temps de céphaline activé.

CONSERVATION, DURÉE DE VIE UTILE ET STABILITÉ

Les flacons de réactif non ouverts sont stables jusqu'à la date de péremption indiquée s'ils sont conservés dans les conditions indiquées sur l'étiquette du kit ou du flacon. Conservez-le à +2° – +8° C. SANS LE CONGELER. Stable pendant 30 jours après ouverture. Évitez des réchauffements prolongés.

PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS

Utiliser tout au long du prélèvement du plastique ou du verre siliconé. Mélanger 9 volumes de sang et 1 volume de citrate de sodium à 3,2% ou 3,8%. Séparer le plasma après centrifugation à 1500 x g pendant 15 minutes. Conserver le plasma entre +2° – +8°C ou +18 – +24°C. L'analyse doit être terminée dans les 4 heures suivant le prélèvement de l'échantillon; sinon, il est possible de congeler le plasma 2 semaines à -20°C ou 6 mois à -70°C. Décongeler rapidement à +37°C avant de réaliser l'analyse. Ne pas laisser à +37°C plus de 5 minutes car la neutralisation de la l'inhibiteur lupique serait réduite[4]. Il est possible d'obtenir des résultats erronés en cas de contamination avec du liquide tissulaire ou en cas de stase. Éviter d'agiter et de former des bulles d'air ou de l'écume. Se référer à Young, *et al.*[5] pour connaître les effets des médicaments couramment administrés.

PROCÉDURE

Méthode Manuelle

1. Préchauffez le mélange d'APTT Si L Minus et de chlorure de calcium à 0,025 M à +37°C.
2. Préchauffez 0,1 mL de plasma à analyser, en dosage double, à +37°C pendant 2 minutes.
3. Ajoutez énergiquement 0,1 mL d'APTT Si L Minus préchauffé au plasma et lancez le coagulomètre. Laissez incuber pendant 5 minutes exactement à +37°C.
4. Ajoutez 0,1 mL de chlorure de calcium à 0,025 M préchauffé.
5. Notez le temps de formation de caillots. Exprimez les résultats TCA en secondes.

Méthodes Automatisées

Consulter le manuel d'utilisation de l'instrument approprié pour obtenir des instructions détaillées ou contacter Helena Biosciences Europe pour obtenir des notes d'application spécifiques à l'instrument.

INTERPRÉTATION DES RÉSULTATS

Les résultats de TCA doivent être relevés en arrondissant au dixième de seconde. Il appartient à chaque laboratoire de déterminer ses valeurs usuelles (en général, temps moyen ± 2 écarts-types). Des résultats dépassant la limite supérieure des valeurs usuelles doivent être considérés comme anormaux et il est nécessaire de réaliser des études plus approfondies. Si les valeurs du TCA sont inférieures à la limite inférieure des valeurs usuelles, répéter l'analyse avec un nouvel échantillon de sang. Un TCA raccourci a été trouvé en association avec des thromboses *in vivo* (par exemple, thrombose veineuse profonde et coagulation intravasculaire disséminée).

Surveillance de l'heparine

Lors de la surveillance de l'héparinothérapie, il est important de créer une courbe de référence *in vitro* qui reflète la réponse moyenne à l'héparine, étant donné que chaque patient répond différemment à l'héparine. On considère en général que la plage thérapeutique de l'héparine se situe entre 0,2 et 0,5 unités/mL[3,6].
Les précautions suivantes doivent être prises en considération lors de la surveillance de l'héparinothérapie:

1. Le moment du prélèvement est important, étant donné la demi-vie *in vivo* de l'héparine n'est que de 1,5 heure[7].
2. Il convient d'éviter que du facteur plaquettaire 4 ne soit libéré (facteur neutralisant l'héparine) en raison de l'agrégation plaquettaire ou de la rupture de la structure lors du prélèvement. Un prélèvement de sang correct, une centrifugation appropriée et un enlèvement rapide de plasma pauvre en plaquettes des globules rouges aide à réduire la libération de facteur plaquettaire 4.
3. Les valeurs initiales du TCA de chaque patient doivent être établies avant la thérapie afin de déterminer le TCA patient respectif puisqu'il se rapporte aux valeurs usuelles établies par le laboratoire.
4. La sensibilité à l'héparine varie en fonction du système de détection de coagulation (mécanique, photo-optique, etc.). Il est nécessaire d'utiliser le même système d'analyse pour la surveillance des patients sous héparine.
5. Les courbes de réponse à l'héparine doivent être déterminées de nouveau lorsque le numéro de lot de réactif change et à des intervalles périodiques avec le même numéro de lot.
6. La courbe de réponse à l'héparine doit être déterminée en utilisant la même héparine tout au long de la thérapie afin d'éliminer les variations dues aux différentes sources d'héparine (par exemple, muqueuse porcine ou poumon bovin).

LIMITES

Les valeurs prévues du TCA varient d'un laboratoire à l'autre suivant la technique utilisée. La méthode de détection du caillot, la température, le pH, la technique de prélèvement, le type d'anticoagulant ainsi que la durée et le mode de conservation de l'échantillon sont des paramètres très importants. Les conditions de prélèvement et de conservation de l'échantillon de plasma doivent être normalisées et soigneusement contrôlées. Tout résultat hors intervalle doit être confirmé par des analyses supplémentaires. La présence de fragments de plaquettes dans un échantillon peut entraîner la libération de phospholipides et, par conséquent, la neutralisation de tout inhibiteur lupique présent dans l'échantillon. Il convient d'éviter d'utiliser des petits volumes de plasma en raison des potentielles variations physiologiques du pH. L'analyse peut être affectée par divers médicaments[5]. Un TCA allongé peut être du à l'administration de diphénylhydantoïne, d'héparine, de warfarine et de substances radiologiques[5,8]. Un TCA raccourci peut être observé en cas d'utilisation de contraceptifs oraux ou chez les sujets sous œstrogénothérapie[9,10]. Il appartient donc à chaque laboratoire d'établir ses propres valeurs attendues pour les patients et de déterminer ses normes de performances pour le contrôle.

CONTRÔLE QUALITÉ

Chaque laboratoire doit établir un programme de contrôle qualité. Les plasmas de contrôle, normaux et anormaux, doivent être testés avant chaque lot d'échantillons patients afin de s'assurer que l'instrument et l'opérateur offrent des performances satisfaisantes. Si les contrôles ne donnent pas les résultats prévus, les résultats du patient doivent être considérés comme non valables.
Helena Biosciences Europe distribue les contrôles suivants à utiliser avec ce produit:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A

VALEURS DE RÉFÉRENCE

Les valeurs de référence peuvent varier d'un laboratoire à l'autre suivant les techniques et les systèmes utilisés. C'est pour cette raison qu'il appartient à chaque laboratoire de déterminer ses propres plages de référence.

CARACTÉRISTIQUES DE PERFORMANCES

Helena Biosciences Europe ou ses mandataires ont déterminé les caractéristiques de performance suivantes en utilisant un instrument de coagulation photo-optique. Chaque laboratoire doit établir ses propres données de performance.

Reproductibilité

	Précision intra-série			Précision inter-séries		
Échantillon	*n*	*Formation du caillot (seconde)*	*CV (%)*	*n*	*Formation du caillot (seconde)*	*CV (%)*
Routine Control N	10	33,0	0,36	100	32,9	2,41
Routine Control SA	10	77,9	0,31	100	78,3	0,77

% Facteur	Facteur VIII (secondes)	Facteur IX (secondes)	Facteur XI (secondes)
<1	85,7	70,9	92,4
10	45,9	44,4	50,7
40	34,2	33,9	34,4
100	28,8	28,8	28,8

Héparine (UI/mL)	Formation du caillot (seconde)
0	29,9
0,2	70,0
0,4	174,0

BIBLIOGRAPHIE

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10. Crowell EB Jr, Clatanoff DV, Kiekhofer W (1971) The effect of oral contraceptives on factor VIII levels, *Lab. Clin. Med,* **77:** 551-7

APTT Si L Minus
Anleitung — de

VERWENDUNGSZWECK

Das APTT Si L Minus-Kit ist für koagulometrische Gerinnungstests vorgesehen.

Zur Bestimmung der aktivierten partiellen Thromboplastinzeit (aPTT) und ähnlichen Gerinnungsverfahren mit Extrakt von Phospholipid und mit nahezu kolloiden Partikeln als Aktivator. Das Testsystem kann mit manuellen, halbautomatischen oder automatischen Methoden angewendet werden. Der APTT-Test wurde durch die Arbeit von Langdell und Mitarbeitern konzipiert[1] und später durch Proctor und Rapaport modifiziert[2], die aPTT wird zum Nachweis von Funktionsstörungen im intrinsischen Gerinnungssystem verwendet, zu welchem die Gerinnungsfaktoren VIII, IX, XI, XII, Präkallikrein und hochmolekulares Kininogen gehören. Die aPTT wird auch bei Tests verwendet, die diese Faktoren quantifizieren, und routinemäßig bei der OP-Vorbereitung und dem Monitoring der Heparintherapie verwendet[3]. Kommerziell erhältliche Reagenzien enthalten üblicherweise einen von drei Aktivatoren: Kaolin, Siliziumdioxid oder Ellagsäure. Bei einem Standard-Screening-Test misst die aPTT indirekt durch ihr Einwirken auf Fibrinogen die Thrombinbildung und damit der Bildung eines Fibringerinnsels. Das zu testende Citratplasma wird im Testansatz mit aPTT-Reagenz bei +37°C über einen bestimmten Zeitraum (üblicherweise 5 Minuten) gemischt und danach vorgewärmtes (+37°C) Calciumchlorid (0,025 M) zugegeben. Mit Zugabe des Calciumchlorids wird die Zeit gestoppt. Die Zeit, die es zur Gerinnselbildung braucht, wird als aPTT bezeichnet. Nachweis der Gerinnselbildung kann mechanisch, manuell (Kippmethode) oder lichtoptisch erfolgen.

WARNHINWEISE UND VORSICHTSMASSNAHMEN

Die in diesem Kit enthaltenen Reagenzien sind ausschließlich für die Verwendung von *in-vitro*-Diagnosen vorgesehen. NICHT VERSCHLUCKEN. Tragen Sie beim Umgang mit sämtlichen Komponenten des Kits geeignete Schutzausrüstung. Beachten Sie gegebenenfalls die Verweise auf entsprechende Gefahren- und Vorbeugeerklärungen in der Produktsicherheitserklärung. Entsorgen Sie die Komponenten gemäß den örtlichen Vorschriften.

ZUSAMMENSETZUNG

Komponente	Inhalt	Beschreibung	Vorbereitung
APTT Si L Minus	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Das Reagenz enthält einen Aktivator aus nahezu kolloiden Partikeln (MagnesiumAluminium-Silikat), mit dem eine optimale Sensitivität gegenüber Faktor-Mangelzuständen und Heparin erreicht wird. Außerdem enthält das Reagenz Phospholipid mit Puffer und Stabilisatoren.	Bringen Sie es vor der Verwendung auf Raumtemperatur. Vor dem Gebrauch gut mischen durch Verwirbeln oder Umdrehen.
Calcium Chloride: 0.025M	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Das Reagenz besteht aus einer 0,025 M Calciumchlorid-Lösung.	Das Reagenz ist gebrauchsfertig verpackt.
Jedes Kit enthält eine Gebrauchsanweisung.			

ERFORDERLICHE, ABER NICHT MITGELIEFERTE ARTIKEL

Es kann jedes zur Durchführung der aktivierten partiellen Thromboplastinzeit geeignete, qualitative hochwertige elektromechanische oder lichtoptische Gerät benutzt werden.

LAGERUNG, HALTBARKEIT UND STABILITÄT

Ungeöffnete Reagenzien sind unter den auf Verpackung oder Fläschchen angegebenen Lagerbedingungen bis zum aufgedruckten Verfallsdatum stabil. Bei +2° – +8°C lagern. NICHT EINFRIEREN. Das Produkt ist nach dem Öffnen 30 Tage lang stabil. Vermeiden Sie lang andauerndes Erhitzen.

PROBENENTNAHME UND VORBEREITUNG

Nur Plastik oder Silikonglas verwenden. Blut (9 Teile) sollte in 3,2% oder 3,8% Natriumcitrat als Antikoagulanz (1 Teil) entnommen werden. 15 Minuten bei 1500 g zentrifugieren und Plasma abpipettieren. Plasma bei +2° – +8°C oder +18 – +24°C lagern. Plasma sollte innerhalb von 4 Stunden verarbeitet oder tief gefroren bei -20°C für 2 Wochen oder -70°C für 6 Monat gelagert werden. Vor dem Testen schnell bei +37°C auftauen. Nicht länger als 5 Minuten bei +37°C belassen[4]; das minimiert die Neutralisation des Lupus-Inhibitors. Fehlerhafte Resultate können durch Kontamination mit Gewebeflüssigkeit oder Stase verursacht werden. Schütteln, Luftblasen oder Schaumbildung vermeiden. Für die Auswirkungen häufig verabreichter Medikamente siehe Young *et al.*[5].

VORGEHENSWEISE

Manuelle Methode

1. Wärmen Sie gut gemischtes APTT Si L Minus und 0,025 M Kalziumchlorid auf +37°C vor.
2. Wärmen Sie zwei Proben des Testplasmas von 0,1 mL 2 Minuten lang auf +37°C vor.
3. Geben Sie 0,1 mL vorgewärmtes APTT Si L Minus zu dem Plasma hinzu, und starten Sie den Timer. Inkubieren Sie genau 5 Minuten lang bei +37°C.
4. Fügen Sie 0,1 mL von den vorgewärmten 0,025 M Kalziumchlorid hinzu.
5. Notieren Sie die Zeit der Gerinnselbildung. Zeichnen Sie das Ergebnis als die aPTT-Zeit in Sekunden auf.

Automatisierte Methoden

Siehe die Bedienungsanleitung des entsprechenden Geräts für genaue Anweisungen oder wenden Sie sich an Helena Biosciences Europe für spezielle anwendungstechnische Hinweise.

INTERPRETATION DER ERGEBNISSE

Die Ergebnisse des aPTT-Tests bis auf ein Zehntel genau in Sekunden angeben. Jedes einzelne Labor sollte seinen Normalbereich (für gewöhnlich X ± 2 s) selbst ermitteln. Ergebnisse über der Grenze des oberen Normalbereichs sollten als abnormal angesehen und der Test wiederholt werden. aPTT-Werte unter dem unteren Normalbereich sollte mit einer frischen Blutprobe wiederholt werden. Verkürzte aPTT-Werte können *in vivo* mit einer Thrombose verbunden beobachtet werden (d. h. tiefe Venenthrombose und Verbrauchskoagulopathie).

Heparin-Monitoring

Bei der Überwachung von Heparin-Therapien ist es wichtig, eine *in vitro* Referenzkurve zu erstellen, welche, da die einzelnen Patienten unterschiedlich auf Heparin reagieren, die durchschnittliche Reaktion auf Heparin widerspiegelt. Im Allgemeinen gilt für Heparin der therapeutische Bereich von 0,2 bis 0,5 Einheiten/mL[3,6].
Folgende Vorsichtsmaßnahmen sollten bei der Überwachung der Heparin-Therapie berücksichtigt werden:

1. Der Zeitpunkt der Entnahme ist wichtig, da Heparin *in vivo* eine Halbwertszeit von nur 1,5 Stunden hat[7].
2. Freisetzung des Plättchenfaktors 4 (Heparin neutralisierender Faktor) durch Thrombozyten-Aggregation oder Schädigung bei der Entnahme sollten vermieden werden. Sorgfältige Blutentnahme, richtiges Zentrifugieren und sofortiges Trennen des plättchenarmen Plasmas von den Zellen trägt dazu bei, die Freisetzung des Plättchenfaktors 4 zu minimieren.
3. Vor der Therapie sollte von jedem Patienten aPTT-Ausgangswerte erstellt werden, um von dem entsprechenden Patienten das aPTT hinsichtlich des von Labor erstellten Normalbereichs zu bestimmen.
4. Die verschiedenen Systeme der Gerinnselerkennung (mechanisch, lichtoptisch usw.) reagieren mit unterschiedlicher Sensibilität auf Heparin. Zur Überwachung heparinisierter Patienten immer dasselbe Testsystem verwenden.
5. Heparin-Reaktionskurven neu erstellen, wenn die Chargen-Nummer des Reagenz sich ändert, und in regelmäßigen Abständen auch innerhalb der gleichen Charge.
6. Die Kurve sollte mit dem Heparin erstellt werden, das auch in der Therapie verwendet wird, um die mit Heparinen aus unterschiedlicher Quelle (z. B. Mucosa vom Schwein oder Lunge vom Rind) verbundenen Variablen auszuschließen.

EINSCHRÄNKUNGEN

Normalwerte für den aPTT-Test variieren je nach angewendeter Technik von Labor zu Labor. Sehr wichtig dafür sind: Methode der Gerinnselerkennung, Temperatur, pH, Entnahmeverfahren, das verwendete Antikoagulanz und Dauer und Art der Probenlagerung. Die Entnahme und Lagerungsbedingungen der Plasmaproben sollten standardisiert sein und sorgfältig überprüft werden. Unerwartete Ergebnisse müssen durch weitere Untersuchungen bestätigt werden. In einer Probe vorhandene Thrombozytenfragmente können die Freisetzung von Phospholipiden verursachen und so eventuell in der Probe vorhandene Lupus-Inhibitoren neutralisieren. Proben mit geringem Plasmavolumen sollten wegen möglicher physiologischer pH-Veränderungen nicht verwendet werden. Die Untersuchung kann durch verschiedene Medikamente beeinträchtigt werden[5]. Eine Verlängerung der aPTT-Ergebnisse kann durch die Gabe von Diphenylhydantoin, Heparin, Warfarin und Röntgenmittel gegeben sein[5,8]. Verminderte aPTT-Werte können bei Einnahme oraler Empfängnisverhütungsmittel oder Östrogentherapie beim Mann beobachtet werden[9,10]. Daher sollten Labors für Patienten ihren eigenen Referenzbereich und klar definierte Leistungsstandards für die Kontrolle erstellen.

QUALITÄTSKONTROLLE

Jedes Labor muss für eine eigene Qualitätskontrolle sorgen.
Vor jeder Testreihe mit Patientenproben müssen normale und pathologische Kontrollplasmen getestet werden, um eine zufrieden stellende Geräteleistung und Bedienung zu gewährleisten. Liegen die Kontrollen außerhalb des Normbereichs, sind die Patientenergebnisse nicht zu verwenden.
In Verbindung mit diesem Produkt bietet Helena Biosciences Europe die folgenden Kontrollen an:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A

REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seine eigenen Referenzwertbereiche erstellen.

LEISTUNGSMERKMALE

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag mit einem fotooptischen Gerinnungsgerät ermittelt. Jede Labor muss seine eigenen Werte ermitteln.

Reproduzierbarkeit

	Intra-assay-Präzision			Inter-assay-Präzision		
Probe	*n*	*Gerinnselbildung (sekunden)*	*CV (%)*	*n*	*Gerinnselbildung (sekunden)*	*CV (%)*
Routine Control N	10	33,0	0,36	100	32,9	2,41
Routine Control SA	10	77,9	0,31	100	78,3	0,77

% Faktor	Faktor VIII (sekunden)	Faktor IX (sekunden)	Faktor XI (sekunden)
<1	85,7	70,9	92,4
10	45,9	44,4	50,7
40	34,2	33,9	34,4
100	28,8	28,8	28,8

Heparin (IU/mL)	Gerinnselbildung (sekunden)
0	29,9
0,2	70,0
0,4	174,0

LITERATURVERZEICHNIS

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APTT Si L Minus
Istruzioni per l'uso

it

SCOPO PREVISTO

Il kit APTT Si L Minus è concepito per l'esecuzione di dosaggi di emostasi basati sulla presenza di coaguli.

Da utilizzare nella determinazione dei tempi di tromboplastina parziale attivata (aPTT), e nelle procedure di coagulazione correlate, con l'impiego di estratto di fosfolipide e particelle paracolloidale come attivatore. Il sistema di test può essere utilizzato con metodi manuali, semiautomatici e automatici. Sin dalle origini, grazie all'opera di Langdell e dei suoi collaboratori[1], modificati successivamente da Proctor e Rapaport[2], il aPTT viene utilizzato per rilevare i disordini del sistema intrinseco della coagulazione, in cui intervengono i fattori della coagulazione VIII, IX, XI e XII, la precallicreina e il chininogeno ad alto peso molecolare. L'aPTT viene utilizzato anche nei dosaggi che quantificano questi fattori e viene abitualmente utilizzato per lo screening prechirurgico e il monitoraggio della terapia eparinica[3]. I reagenti disponibili in commercio impiegano solitamente uno dei 3 attivatori seguenti: caolino, silice o acido ellagico. Nel test di screening di base, il aPTT misura indirettamente la formazione di trombina grazie alla sua azione sul fibrinogeno che forma il coagulo di fibrina. Nel test, il plasma citrato di prova viene miscelato con il reagente per aPTT per un intervallo di tempo specifico (solitamente di 5 minuti) a +37°C, seguito dall'aggiunta di calcio cloruro (0,025 M) preriscaldato (+37°C). La misurazione del tempo ha inizio al momento dell'aggiunta del calcio cloruro. Il tempo necessario per la formazione del coagulo corrisponde al aPTT. Il rilevamento del coagulo può avvenire per misurazione meccanica, manuale (inclinazione della provetta) o foto-ottica.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere le relative indicazioni precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
APTT Si L Minus	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Il reagente contiene un attivatore di particelle paracolloidale (silicato di magnesio ed alluminio) per una maggior sensibilità nei confronti di deficit di fattori e dell'eparina. Il reagente contiene inoltre un fosfolipide con tampone e stabilizzatori.	Prima dell'uso portare a temperatura ambiente. Miscelare accuratamente con il vortex o capovolgere più volte prima di utilizzare il reagente.
Calcium Chloride: 0.025M	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	Il reagente è costituito da una soluzione 0,025 M di calcio cloruro.	Il reagente è in confezione pronta all'uso.

Ogni kit contiene un Istruzioni per l'uso.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

È possibile utilizzare qualsiasi strumento di coagulazione elettromeccanico o foto-ottico di alta qualità idoneo alla determinazione dei tempi di tromboplastina parziale attivata.

CONSERVAZIONE, VITA UTILE E STABILITÀ

I reagenti non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sul flacone o sull'etichetta del kit. Conservare a una temperatura compresa tra +2° –+8°C. NON CONGELARE. Il reagente rimane stabile per 30 giorni dopo l'apertura. Evitare il riscaldamento prolungato.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Nel corso dell'intera procedura è necessario utilizzare plastica o vetro siliconizzato. Il sangue (9 parti) deve essere raccolto in sodio citrato al 3,2% o al 3,8% come anticoagulante (1 parte). Separare il plasma in seguito a centrifugazione a 1500 x g per 15 minuti. Il plasma deve essere conservato a +2° –+8°C o +18 –+24°C. I test devono essere completati entro 4 ore dalla raccolta dei campioni; in alternativa, il plasma può essere conservato congelato a -20°C per 2 settimane o a -70°C per 6 mese. Decongelare rapidamente a +37°C prima di eseguire i test. Non conservare a +37°C per oltre 5 minuti[4]. Ciò ridurrà al minimo la neutralizzazione del lupus inibitore. La contaminazione con liquidi tissutali o la stasi possono dare luogo a risultati erronei. Evitare l'agitazione, le bolle d'aria o la formazione di schiuma. Per gli effetti dei farmaci comunemente somministrati fare riferimento a Young *et al.*[5].

PROCEDURA

Metodo Manuale

1. Miscelare accuratamente APTT Si L Minus e il calcio cloruro a 0,025 M quindi preriscaldare a +37°C.
2. Preriscaldare 0,1 mL di plasma di test, in doppio, a +37°C per due minuti.
3. Aggiungere forzatamente 0,1 mL di reagente APTT Si L Minus preriscaldato al plasma e avviare il cronometro. Incubare per esattamente 5 minuti a +37°C.
4. Aggiungere 0,1 mL di calcio cloruro preriscaldato a 0,025 M.
5. Prendere nota del tempo necessario per la formazione di coaguli. Riportare il risultato come tempo aPTT in secondi.

Metodo Automatico

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europe per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

I risultati del test aPTT devono essere registrati con un'approssimazione di 1/10 di secondo. Per ogni singolo laboratorio dovrebbe essere stabilito il range normale (di solito X ± 2 deviazioni standard). I risultati maggiori dei limiti superiori del range normale devono essere considerati anomali e devono pertanto essere eseguiti test di follow-up. I valori di aPTT minori dei limiti inferiori del range normale devono essere ripetuti su un nuovo campione di sangue. Valori di aPTT breve possono essere osservati in concomitanza con una trombosi *in vivo* (ossia trombosi delle vene profonde e coagulazione intravascolare disseminata).

Monitoraggio dell'eparina

In caso di monitoraggio della terapia eparinica, è importante costruire una curva di riferimento *in vitro* che rifletta la risposta media all'eparina, in quanto i singoli pazienti rispondono all'eparina in modo diverso. In generale, il range terapeutico per l'eparina può essere considerato compreso tra 0,2 e 0,5 unità/mL[3,6].
Durante il monitoraggio della terapia eparinica, è necessario adottare le misure precauzionali illustrate di seguito:

1. Il tempo di raccolta è importante, in quanto l'eparina possiede un'emivita *in vivo* di appena 1,5 ore[7].
2. È necessario evitare il rilascio del fattore piastrinico 4 (fattore di neutralizzazione dell'eparina) causato dall'aggregazione delle piastrine o eventuali danni durante la raccolta. Un'attenta raccolta del sangue, una centrifugazione adeguata e una tempestiva rimozione del plasma povero di piastrine dalle cellule contribuiscono a ridurre al minimo il rilascio del fattore piastrinico 4.
3. I dati di base sull'aPTT di ciascun paziente devono essere definiti prima della terapia, per determinare il rispettivo aPTT correlato al range normale stabilito dal laboratorio.
4. I diversi sistemi di rilevamento del coagulo (meccanica, foto-ottici, ecc.) mostrano sensibilità variabili all'eparina. Durante il monitoraggio dei pazienti eparinizzati è necessario utilizzare lo stesso sistema di test.
5. Le curve di risposta all'eparina devono essere determinate nuovamente con il cambiamento dei numeri di lotto del reagente e ad intervalli periodici con lo stesso numero di lotto.
6. La curva deve essere costruita utilizzando anche la stessa eparina impiegata in terapia, per eliminare le variabili collegate alle eparine provenienti da fonti diverse (ad es. mucosa suina o polmone bovino).

LIMITAZIONI

I valori previsti per il test dell'aPTT variano da un laboratorio all'altro in funzione della tecnica utilizzata. Il metodo di rilevamento del coagulo, la temperatura, il pH, la tecnica di raccolta, il tipo di anticoagulante, nonché il tempo e il metodo di conservazione dei campioni sono tutti fattori estremamente importanti. Le condizioni di raccolta e conservazione dei campioni di plasma devono essere standardizzate ed attentamente controllate. I risultati imprevisti devono essere confermati da ulteriori test. I frammenti di piastrine presenti in un campione possono causare il rilascio di fosfolipidi e pertanto la neutralizzazione di un eventuale lupus inibitore contenuto nel campione stesso. Deve essere evitato l'utilizzo di campioni con piccoli volumi plasmatici in ragione delle possibili variazioni fisiologiche di pH. I test possono essere influenzati da svariati farmaci[5]. Un aumento dei risultati dell'aPTT può essere attribuito alla somministrazione di difenilidantoina, eparina, warfarin e agenti radiografici[5,8]. Una riduzione dei valori di aPTT può essere osservata durante l'impiego di contraccettivi orali o nelle terapie estrogeniche maschili[9,10]. Pertanto, i laboratori dovranno determinare i propri valori previsti per i pazienti e precisi standard prestazionali per il controllo.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.
Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A

VALORI DI RIFERIMENTO

Per la sicurezza del paziente, è necessario che il sistema sia monitorato continuamente da un operatore qualificato. Per tale motivo ciascun laboratorio dovrà elaborare i propri range di riferimento.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione foto-ottico. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali.

Riproducibilità

		Precisione intra-dosaggio		Precisione tra i dosaggi		
Campione	*n*	*Formazione del coagulo (secondi)*	*CV (%)*	*n*	*Formazione del coagulo (secondi)*	*CV (%)*
Routine Control N	10	33,0	0,36	100	32,9	2,41
Routine Control SA	10	77,9	0,31	100	78,3	0,77

% Fattore	Fattore VIII (secondi)	Fattore IX (secondi)	Fattore XI (secondi)
<1	85,7	70,9	92,4
10	45,9	44,4	50,7
40	34,2	33,9	34,4
100	28,8	28,8	28,8

Eparina (IU/mL)	Formazione del coagulo (secondi)
0	29,9
0,2	70,0
0,4	174,0

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10. Crowell EB Jr, Clatanoff DV, Kiekhofer W (1971) The effect of oral contraceptives on factor VIII levels, *Lab. Clin. Med,* **77:** 551-7

APTT Si L Minus
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit APTT Si L Minus es realizar ensayos de hemostasia basados en la coagulación.

Para usar en la determinación de los tiempos de tromboplastina parcial activada (TTPa), y procedimientos de coagulación relacionados usando extracto de fosfolípido con de partículas casi-coloidal como activador. El sistema de prueba puede usarse con métodos manuales, semiautomatizados y automatizados. Desde su definición por parte de Langdell et al[1] y tras diversas aportaciones de Proctor y Rapaport[2], el TTPa se utiliza para detectar trastornos del sistema de coagulación intrínseco, que implica a los factores de coagulación VIII, IX, XI, XII, precalicreína y cininógeno de alto peso molecular. El TTPa se usa también en ensayos que cuantifican estos factores y se usa rutinariamente para el cribado prequirúrgico y la monitorización del tratamiento con heparina[3]. Los reactivos disponibles comercialmente usan normalmente uno de tres activadores: caolín, sílice o ácido elágico. En la prueba de cribado básica, el TTPa mide indirectamente la formación de trombina por su acción sobre el fibrinógeno que forma el coágulo de fibrina. En la prueba, el plasma de prueba citratado se mezcla con reactivo de TTPa durante un período de tiempo especificado (normalmente 5 minutos) a +37°C seguido por la adición de cloruro cálcico (0,025 M) precalentado (+37°C). La temporización comienza desde el momento de la adición de cloruro cálcico. El tiempo necesario para la formación del coágulo es el TTPa. La detección de coágulos puede hacerse mediante medición mecánica, manual (tubo inclinado) o fotoóptica.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*: NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
APTT Si L Minus	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	El reactivo contiene un activador de partículas casi-coloidal (magnesio-aluminiosilicato) que permite una sensibilidad óptima frente a los déficits de factor y frente a la heparina. El reactivo contiene asimismo un fosfolípido con tampón y estabilizadores.	Antes de utilizar, esperar a que alcance la temperatura ambiente. Antes de utilizar mezclar bien mediante agitación suave o inversión.
Calcium Chloride: 0.025M	5 x 5 mL (REF 5562) 10 x 5 mL (REF 5560) 10 x 10 mL (REF 5559)	El reactivo es una solución de cloruro cálcico 0,025 M.	El reactivo viene envasado listo para usar.

Cada kit contiene instrucciones de uso.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

Puede usarse cualquier instrumento de coagulación electromecánico o foto-óptico diseñado para realizar pruebas de tiempos de tromboplastina parcial activada.

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los reactivos no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit. Conservar a una temperatura entre +2° –+8°C. NO CONGELAR. Tras su apertura, el producto es estable durante 30 días. Evitar un calentamiento prolongado.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

Debe usarse siempre plástico o vidrio siliconizado. Debe recogerse sangre (9 partes) en el anticoagulante citrato sódico al 3,2% o al 3,8% (1 parte). Separar el plasma después de la centrifugación a 1500 x g durante 15 minutos. El plasma debe conservarse a +2° –+8°C o +18 –+24°C. Las pruebas deberían terminarse en 4 horas desde la recogida de las muestras o el plasma puede conservarse congelado a -20°C durante 2 semanas o -70°C durante 6 mes. Descongelar rápidamente a +37°C antes de realizar la prueba. No conservar a +37°C durante más de 5 minutos[4]. Esto minimizará la neutralización del inhibidor lupus. Pueden producirse resultados erróneos por contaminación con líquidos tisulares o estasia. Evitar la agitación, las burbujas de aire o la formación de espuma. Para comprobar los efectos de los fármacos que se suelen administrar, consultar Young, *et al.*[5].

PROCEDIMIENTO

Método Manual

1. Precalentar a +37°C el APTT Si L Minus y el cloruro cálcico 0,025 M bien mezclados.
2. Precalentar 0,1 mL de plasma problema, por duplicado, a +37°C durante 2 minutos.
3. Añadir 0,1 mL de APTT Si L Minus precalentado al plasma y activar el temporizador. Incubar durante exactamente 5 minutos a +37°C.
4. Añadir 0,1 mL de cloruro cálcico 0,025 M precalentado.
5. Anotar el momento de la formación del coágulo. Registrar el resultado como tiempo TTPa (en segundos).

Método Automatizado

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE LOS RESULTADOS

Los resultados de la prueba de TTPa deben comunicarse a la décima de segundo más próxima. Cada laboratorio debe establecer el intervalo normal (habitualmente, X ± 2 desviaciones estándar). Los resultados mayores que los límites superiores del intervalo normal deben considerarse anormales y deben realizarse pruebas de seguimiento. Cualquier valor de TPPa menor que los límites inferiores del intervalo normal deben repetirse en una nueva muestra de sangre. Pueden verse valores de TTPa cortos en asociación con la trombosis *in vivo* (p. ej., trombosis venosa profunda y coagulación intravascular diseminada).

Monitorización de la heparina

Cuando monitorice el tratamiento con heparina, es importante construir una curva de referencia *in vitro* que refleje el promedio de respuesta de la heparina, porque los pacientes individuales responden de forma diferente a la heparina. En general, se puede considerar el intervalo terapéutico para la heparina como de 0,2 a 0,5 unidades/mL[3,6].
Deben considerarse las siguientes precauciones a la hora de monitorizar el tratamiento con heparina:

1. El momento de la recogida es importante, porque la heparina tiene una semivida *in vivo* de sólo 1,5 horas[7].
2. Debe evitarse la liberación de factor 4 plaquetario (factor neutralizador de heparina) ocasionada por la agregación plaquetaria o por daños durante la recogida. Una recogida de sangre cuidadosa, una buena centrifugación y una eliminación rápida del plasma pobre en plaquetas de las células, contribuirán a minimizar la liberación de factor 4 plaquetario.
3. Deben establecerse datos basales sobre los TTPa de cada paciente antes del tratamiento para determinar el TTPa respectivo del paciente ya que se relaciona con el intervalo normal establecido por el laboratorio.
4. Sistemas de detección de coágulos distintos (mecánica, fotoópticos, etc.) muestran sensibilidades variables a la heparina. Debe utilizarse el mismo sistema de prueba a la hora de monitorizar pacientes heparinizados.
5. Deben reestablecerse las curvas de respuesta a la heparina cuando cambien los números de lote de los reactivos y a intervalos periódicos con el mismo número de lote.
6. Debe construirse también la curva usando la misma heparina empleada en el tratamiento para eliminar las variables relacionadas con las heparinas de fuentes diferentes (p. ej., mucosa porcina o pulmón bovino).

LIMITACIONES

Los valores esperados para la prueba de TTPa variarán de un laboratorio a otro, dependiendo de la técnica usada. El método de detección de los coágulos, la temperatura, el pH, la técnica de recogida, el tipo de anticoagulante y el tiempo y el método de almacenamiento de la muestra son todos muy importantes. Las condiciones de recogida y conservación de las muestras de plasma deben estandarizarse y controlarse cuidadosamente. Los resultados inesperados deben confirmarse mediante pruebas adicionales. Los fragmentos plaquetarios presentes en una muestra pueden ocasionar la liberación de fosfolípidos y, con ello, la neutralización de cualquier inhibidor lupus presente en la muestra. Debe evitarse el uso de muestras con volúmenes pequeños de plasma debido a posibles cambios fisiológicos de pH. Las pruebas pueden verse afectadas por diversos fármacos[5]. Un aumento en los resultados de TTPa puede estar causado por la administración de difenilhidantoina, heparina, warfarina y agentes radiográficos[5,8]. Se puede comprobar un descenso en los valores de TTPa mientras se usan contraceptivos orales o tratamientos con estrógenos para hombres[9,10]. Por ello, los laboratorios deben establecer sus propios valores esperados para pacientes y estándares de rendimiento bien definidos para el control.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los controles normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.
Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer sus propios intervalos de referencia.

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación foto-óptico. Cada laboratorio debe establecer sus propios datos de rendimiento.

Riproducibilità

		Precisión intra-ensayo		Precisión inter-ensayo		
Muestra	*n*	*Formación del coágulo (segundo)*	*CV (%)*	*n*	*Formación del coágulo (segundo)*	*CV (%)*
Routine Control N	10	33,0	0,36	100	32,9	2,41
Routine Control SA	10	77,9	0,31	100	78,3	0,77

% Factor	Factor VIII (segundo)	Factor IX (segundo)	Factor XI (segundo)
<1	85,7	70,9	92,4
10	45,9	44,4	50,7
40	34,2	33,9	34,4
100	28,8	28,8	28,8

Heparina (IU/mL)	Formación del coágulo (segundo)
0	29,9
0,2	70,0
0,4	174,0

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Тест-система "Активированное частичное тромбопластиновое время (кремниевый активатор L минус)"
инструкция

ru

НАЗНАЧЕНИЕ

Комплект APTT Si L Minus предназначен для выполнения анализов гемостаза на основе кровяного сгустка.

Используется для определения активированного частичного тромбопластинового времени (АЧТВ) и сопутствующих процессов коагуляции с использованием фосфолипидного экстракта и активатора околоколлоидных частиц. Тестовая система может использоваться в ручном, полуавтоматическом и автоматическом режиме. С момента возникновения, в работе Лангделла и его коллег[1] и позднее переработанный Проктором и Рапапортом[2] показатель АЧТВ используется для определения нарушений во врожденной системе коагуляции, которая включает факторы коагуляции VIII, IX, XI, XII, прекалликреин и высокомолекулярный кининоген. АЧТВ также используется в анализах для подсчета данных факторов и обычно используется для скрининга и мониторинга гепариновой терапии перед хирургическим вмешательством. Антифосфолипидные антитела и неспецифичные ингибиторы (волчаноподобные антикоагулянты) могут стать причиной пролонгированных значений АЧТВ. Однако признано, что данный эффект связан с концентрацией ингибитора и является непоследовательным[3]. Реагенты доступные в торговой сети обычно используют один из трех активаторов: каолин, кремень или эллаговую кислоту. В базовом скрининговом исследовании активированное частичное тромбопластиновое время косвенно измеряет образование тромбина путем воздействия на фибриноген, формирующий фибриновые тромбы. В исследовании цитратная тестируемая плазма смешивается с реагентом АЧТВ в течение указанного промежутка времени (обычно 5 минут) при температуре +37°C, после чего добавляется предварительно подогретый хлорид кальция (0,025 M). Отсчет времени начинается со времени добавления хлорида кальция. Время, требуемое для образования тромбов, является АЧТВ. Определение тромбов может происходить путем механического, фотооптического измерения или вручную (наклонная пробирка).

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

СОСТАВ

Состав	Содержание набора	Описание	Приготовление
АЧТВ (кремниевый активатор L минус)	5 x 5 mL (Кат. № 5562) 10 x 5 mL (Кат. № 5560) 10 x 10 mL (Кат. № 5559)	Реагент содержит активатор околоколлоидных частиц (силикат магния-алюминия) для оптимальной чувствительности к дефицитам фактора и к гепарину. Реагент также содержит фосфолипиды с буфером.	Доведите до комнатной температуры перед использованием. Хорошо перемешайте вращательными движениями или путем переворачивания перед использованием.
Хлорид кальция 0,025M	5 x 5 mL (Кат. № 5562) 10 x 5 mL (Кат. № 5560) 10 x 10 mL (Кат. № 5559)	Реагент представляет собой раствор хлорида кальция 0,025 M.	Реагент готов к использованию.

В каждом наборе имеется инструкция по применению.

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Может использоваться любой высококачественный электромеханический или фотооптический коагулометр для измерения АЧТВ.

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Невскрытые флаконы остаются стабильными до истечения срока годности при хранении в условиях, указанных на флаконе или этикетке набора. Не замораживайте. Стабильность сохраняется в течение 30 дней после вскрытия. Избегайте длительного нагревания.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Для работы следует использовать только пластиковые или силиконизированные стеклянные пробирки. Кровь (9 частей) забирается в пробирку с антикоагулянтом цитрата натрия 3,2% или 3,8% (1 часть). Отделите плазму после центрифугирования при 1500 g в течение 15 минут. Плазму следует хранить при температуре +2° –+8°C или +18 –+24°C. Исследование должно быть завершено в течение 4 часов после забора образцов, либо плазму можно заморозить при -20°C и хранить 2 недели, а при замораживании при -70°C она может храниться в течение 6 месяцев. Размораживайте быстро при +37°C до проведения исследования. Не держите более 5 минут при температуре +37°C[4].

ПРОЦЕДУРА

Ручной Метод

1. Предварительно нагрейте хорошо перемешанную тест-систему и хлорид кальция 0,025 M до +37°C.
2. Предварительно нагрейте две части исследуемой плазмы, по 0,1 мл каждая, до +37°C в течение 2 минут.
3. Принудительно добавьте 0,1 мл предварительно нагретую тест-систему к плазме и включите таймер. Инкубируйте точно 5 минут при температуре +37°C.
4. Добавьте 0,1 мл согретого хлорида кальция 0,025 M.
5. Отметьте время образования тромбов. Результаты отразите как АЧТВ (в секундах).

Автоматизированный Метод

Обратитесь к соответствующей инструкции по эксплуатации прибора за подробной информацией или обратитесь в компанию "Хелена Байосайенсес Европ" за получением справочной информации применительно к конкретному прибору.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Результаты теста на АЧТВ должны указываться до ближайшей 1/10 секунды. Нормальный диапазон (обычно X±2 стандартные отклонения) должен устанавливаться для каждой лаборатории. Результаты, превышающие верхние пороговые значения нормального диапазона должны считаться атипичными и должно проводиться последующее исследование. Любые значения АЧТВ меньше нижних пороговых значений нормального диапазона должны быть повторены на новом образце крови. Низкие значения АЧТВ могут ассоциироваться с тромбозом в организме (например, тромбозом глубоких вен и распространенной внутрисосудистой коагуляцией).

Мониторинг гепарина

При мониторинге гепариновой терапии важно построить калибровочную лабораторную кривую, которая отражает среднее значение гепаринового ответа, поскольку разные пациенты по-разному реагируют на гепарин. В целом, можно считать, что терапевтический диапазон для гепарина составляет от 0,2 до 0,5 ЕД/мл[3,6].
Следует принимать во внимание следующие предостережения при мониторинге гепариновой терапии:

1. Время забора имеет значение, так как время полувыведения гепарина в организме составляет только 1,5 часа[7].
2. Необходимо избегать высвобождения фактора тромбоцита 4 (фактор нейтрализации гепарина), вызванного агрегацией тромбоцитов или повреждением в ходе забора. Осторожный забор крови, правильное центрифугирование и быстрое удаление плазмы бедной на тромбоциты из клеток поможет минимизировать высвобождение фактора тромбоцитов 4.
3. Исходные данные о АЧТВ каждого пациента должны быть установлены до проведения терапии для определения АЧТВ соответствующего пациента в соотношении с нормальным диапазоном, установленным лабораторией.
4. Разные системы определения тромбов (механическая, фотооптическая и др.) демонстрируют разную чувствительность к гепарину. Такая же система исследования должна использоваться при мониторинге пациентов, которым проводится гепариновая терапия.
5. Кривые гепаринового ответа должны быть построены повторно при изменении номеров партий реагентов и через периодические интервалы для одной и той же партии.
6. Кривая также должна быть построена с использованием такого же гепарина, который применялся в терапии, во избежание колебаний, связанных с гепарином, взятым из разных источников (например, свиная слизистая оболочка или бычье легкое).

ОГРАНИЧЕНИЯ

Ожидаемые результаты исследования на АЧТВ будут различными в разных лабораториях в зависимости от используемого метода. Метод клоттингового определения, температура, pH, техника забора, тип антикоагулянта, время и способ хранения образца очень важны. Забор образца плазмы и условия хранения должны быть стандартизованы и тщательно контролироваться. Непредвиденные результаты должны быть подтверждены дополнительными тестами. Фрагменты тромбоцитов, имеющиеся в пробе, могут высвободить фосфолипиды и тем самым нейтрализацию любого ингибитора волчанки, имеющегося в пробе. Необходимо избегать использования проб с небольшим объемом плазмы ввиду возможных изменений физиологического pH. На результаты исследования могут оказать влияние некоторые лекарственные средства[5]. Повышенный уровень АЧТВ может быть вызван приемом дифенилгидантоина, гепарина, варфарина и радиографических веществ[5,8]. Сниженные показатели АЧТВ могут наблюдаться в ходе приема оральных контрацептивов или эстрогеновой терапией у мужчин[9,10]. То есть, лаборатории должны устанавливать свои собственные ожидаемые значения для пациентов, а также четкие стандарты для контроля рабочих характеристик.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна иметь программу контроля качества. Нормальная контрольная плазма и контрольная плазма с отклонениями должны тестироваться перед каждой партией образцов плазмы пациентов для обеспечения правильной работы прибора и лаборанта. Если контрольные образцы не дают ожидаемых результатов, результаты анализа образцов пациентов считаются недействительными.
Компания "Хелена Байосайенсес Европ" предоставляет следующие контрольные образцы для использования с данным продуктом:

Кат. № 5186	Контроль качества, норма
Кат. № 5187	Контроль качества, умеренно выраженная патология
Кат. № 5183	Контроль качества, высокая патология
Кат. № 5301	Контроль качества специальные тесты, норма
Кат. № 5302	Контроль качества специальные тесты, патология

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Контрольные значения могут быть различными в разных лабораториях, в зависимости от используемых методов и систем. В связи с этим каждая лаборатория должна установить собственные показатели контрольных диапазонов.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Следующие рабочие характеристики были определены компанией "Хелена Байосайенсес Европ" или ее представителями с использованием фотооптического коагулометра. Каждая лаборатория должна установить собственные рабочие характеристики.

Изучение повторяемости

		Внутрианалитическая сходимость		Внутрианалитическая сходимость		
Образец	*Число образцов*	*Образование тромбов (секунды)*	*CV (%)*	*Число образцов*	*Образование тромбов (секунды)*	*CV (%)*
Контроль качества, норма	10	33,0	0,36	100	32,9	2,41
Контроль качества, высокая патология	10	77,9	0,31	100	78,3	0,77

% Фактор	Фактор VIII (секунды)	Фактор IX (секунды)	Фактор XI (секунды)
<1	85,7	70,9	92,4
10	45,9	44,4	50,7
40	34,2	33,9	34,4
100	28,8	28,8	28,8

Гепарин (МЕ/мл)	Образование тромбов (секунды)
0	29,9
0,2	70,0
0,4	174,0

ЛИТЕРАТУРА

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Declaration of Conformity

HL-7- 0512 DC DOI 2013/08 (4)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5556	Clauss Fibrinogen 50	55997
5556H	Clauss Fibrinogen 50	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

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Title: Managing Director

Signed:

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Clauss Fibrinogen 50

REF 5556
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HL-2-1771P 2012/03 (7)

Clauss Fibrinogen 50
Instructions for use — en

INTENDED USE

For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on Helena Biosciences Europe AC-4, C-1, C-2, C-4 Coagulation Systems.

Clauss Fibrinogen 50 is intended for the quantitative determination of fibrinogen in human plasma. Clauss[1] developed a simple method for the quantitative determination of fibrinogen by measuring the clotting time of dilute plasma after the addition of Thrombin (>30 NIH units/mL). This clot time is proportional to the fibrinogen concentration. Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use[2]. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenaemia (no detectable fibrinogen), hypofibrinogenaemia (<1 mg/mL) and dysfibrinogenaemia (abnormal fibrinogen molecule).

WARNINGS AND PRECAUTIONS

The reagents contained in this kit are for *in vitro* diagnostic use only - DO NOT INGEST. Wear gloves when handling all kit components. Refer to the product safety data sheets for risk and safety phrases and disposal information. Plasma products have been screened and found negative (unless otherwise stated on the kit box or vial) for the presence of Hepatitis B Antigen (HbsAg) HIV 1 and 2 antibody and HCV antibody; however they should be handled with the same precautions as a human plasma sample.

COMPOSITION

Component	Content	Description	Preparation
Thrombin: 50 NIH/mL	5 x 4 mL (REF 5556) 5 x 2 mL (REF 5556H)	Contains approximately 200 (REF 5556) / 100 (REF 5556H) units bovine thrombin with stabilisers.	Reconstitute each vial with: 4 mL (REF 5556) 2 mL (REF 5556H) of purified water. Take care when pipetting to avoid contamination. Swirl gently and allow to stand for 15 minutes. Mix well immediatley before use. Do not shake.
Fibrinogen Calibrator	2 x 1 mL (REF 5556) 1 x 1 mL (REF 5556H)	Contains 1 mL of lyophilised normal human plasma assayed for fibrinogen levels.	Reconstitute each vial with exactly 1 mL of purified water. Swirl gently and allow to stand for 10 minutes. Mix gently before use. Do not shake.
Owren's Buffer	2 x 25 mL (REF 5556) 1 x 25 mL (REF 5556H)	Contains 25 mL of buffer which contains barbital and sodium chloride and sodium azide as preservative.	The buffer is ready for use as packaged.
Each kit contains instructions for use.			
Each kit contains lot specific reference values insert.			

ITEMS REQUIRED BUT NOT PROVIDED

Refer to the Instrument Operator Manual and/or application note for appropriate instructions. The reagents contained in this kit are also available as separate items:

REF 5374	Clauss Fibrinogen (Thrombin only)
REF 5378	Clauss Fibrinogen (Thrombin only)
REF 5379	Fibrinogen Calibrator
REF 5375	Owren's Buffer

STORAGE AND STABILITY

Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label.

Thrombin: 50 NIH/mL	Once reconstituted, the reagent is stable for 8 hours at $^{+}$15 –$^{+}$30°C, 1 week at $^{+}$2 –$^{+}$8°C or 1 month at -20°C.
Fibrinogen Calibrator	Once reconstituted, the reagent is stable for 4 hours at $^{+}$2 –$^{+}$8°C.
Owren's Buffer	Store at $^{+}$2 –$^{+}$8°C once opened.

SAMPLE COLLECTION AND PREPARATION

Plastic or siliconised glass should be used throughout. Blood (9 parts) should be collected into 3.2% or 3.8% sodium citrate anticoagulant (1 part). Separate plasma after centrifugation at 1500 x g for 15 minutes. Plasma should be kept at $^{+}$2 –$^{+}$8°C or $^{+}$18 –$^{+}$24°C. Testing should be completed within 4 hours of sample collection, or plasma can be stored frozen at -20°C for 2 weeks or -70°C for 6 months. Thaw quickly at $^{+}$37°C prior to testing. Do not keep at $^{+}$37°C for more than 5 minutes[3].

PROCEDURE

Refer to the appropriate instrument Operator Manual for detailed instructions or contact Helena Biosciences Europe for instrument specific application guides.

INTERPRETATION OF RESULTS

Expected values for fibrinogen in healthy adults are 150-350 mg/dL (1.5-3.5 g/L)[4,5].

LIMITATIONS

Heparin levels >0.6 units/mL and fibrinolytic degredation products >100 mg/mL may cause falsely low fibrinogen quantitation. If values fall outside the standard curve values for the patient samples, re-assay using an appropriate dilution to bring values into the standard range.

QUALITY CONTROL

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid. Helena Biosciences Europe supply the following controls available for use with this product:

REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A
REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA

REFERENCE VALUES

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own normal range.

PERFORMANCE CHARACTERISTICS

Helena Biosciences Europe or their representatives have determined the following performance characteristics as a guideline. Each laboratory should establish its own performance data. The Clauss Fibrinogen assay is designed to give a linear calibration from 1.5 - 6.5 g/L.

Reproducibility

Intra-assay precision			Inter-assay precision		
Fibrinogen (g/L)	***n***	***CV (%)***	***Fibrinogen (g/L)***	***n***	***CV (%)***
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

REFERENCES

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
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3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
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Clauss Fibrinogen 50
Fiche technique — fr

UTILISATION

Sert à la détermination quantitative du fibrinogène, selon la méthode de Clauss, dans le plasma humain citraté avec les analyseurs de coagulation Helena Biosciences Europe AC-4, C-1, C-2, C-4.

Le kit de Fibrinogène Clauss 50 est utilisé pour la détermination quantitative du fibrinogène dans le plasma humain. Clauss[1] a développé une méthode simple de détermination quantitative du fibrinogène en mesurant le temps de coagulation de plasma dilué après l'ajout de Thrombin (>30 unités NIH/mL). Ce temps de coagulation est proportionnel à la concentration en fibrinogène. Le taux de fibrinogène peut augmenter en raison d'une inflammation, d'une grossesse ou de la prise de contraceptifs oraux[2]. Des taux diminués sont trouvés dans certaines pathologies comme une maladie du foie ou une CIVD. L'afibrinogénémie (pas de fibrinogène détectable), l'hypofibrinogénémie (<1 mg/mL) et la dysfibrinogénémie (molécule de fibrinogène anormale) sont des anomalies congénitales.

AVERTISSEMENTS ET PRÉCAUTIONS

Les réactifs du kit sont à usage diagnostic *in vitro* uniquement - NE PAS INGÉRER. Porter des gants pour la manipulation de tous les composants. Se reporter aux fiches de sécurité des composants du kit pour la manipulation et l'élimination. Un dépistage des produits à base de plasma a été réalisé et a donné un résultat négatif (sauf indication contraire sur la boîte du kit ou sur le flacon) pour les antigènes de l'hépatite B (AgHBs), les anticorps anti VIH 1 et 2 et les anticorps anti VHC; il est malgré tout nécessaire de les manipuler avec les mêmes précautions que pour les échantillons de plasma humain.

COMPOSITION

Composant	Contient	Description	Préparation
Thrombin: 50 NIH/mL	5 x 4 mL (REF 5556) 5 x 2 mL (REF 5556H)	Chaque flacon contient environ 200 (REF 5556) / 100 (REF 5556H) unités de Thrombin bovine additionnée de stabilisateurs.	Reconstituer chaque flacon avec: 4 mL (REF 5556) 2 mL (REF 5556H) d'eau distillée. Faire attention lors du pipetage pour éviter toute contamination. Remuer doucement et laisser reposer 15 minutes. Bien mélanger juste avant utilisation. Ne pas agiter.
Fibrinogen Calibrator	2 x 1 mL (REF 5556) 1 x 1 mL (REF 5556H)	Chaque flacon contient 1 mL de plasma humain normal lyophilisé dosé pour les taux de fibrinogène.	Reconstituer chaque flacon avec exactement 1,0 mL d'eau distillée. Remuer doucement et laisser reposer 10 minutes. Mélanger doucement avant utilisation. Ne pas agiter.
Owren's Buffer	2 x 25 mL (REF 5556) 1 x 25 mL (REF 5556H)	Chaque flacon contient 25 mL de tampon contenant du barbital et du chlorure de sodium additionné d'azide de sodium comme conservateur.	Le tampon est prêt à l'emploi.
Chaque kit contient une fiche technique.			
Chaque kit contient valeurs de référence spécifiques du lot.			

MATÉRIELS NÉCESSAIRES NON FOURNIS

Se référer au manuel d'utilisation de l'instrument et/ou aux notes d'application pour avoir des instructions appropriées. Les réactifs du kit sont aussi disponibles séparément:

REF 5374	Clauss Fibrinogen (Thrombin only)
REF 5378	Clauss Fibrinogen (Thrombin only)
REF 5379	Fibrinogen Calibrator
REF 5375	Owren's Buffer

CONSERVATION ET STABILITÉ

Les flacons non ouverts sont stables jusqu'à la date de péremption indiquée s'ils sont conservés dans les conditions indiquées sur l'étiquette du kit ou du flacon.

Thrombin: 50 NIH/mL	Une fois reconstitué, le réactif est stable 8 heures à température ambiante, 1 semaine entre $^{+}$2 –$^{+}$8°C ou 1 mois à -20°C.
Fibrinogen Calibrator	Une fois reconstitué, le réactif est stable 4 heures entre $^{+}$2 –$^{+}$8°C.
Owren's Buffer	Conserver entre $^{+}$2 –$^{+}$8°C une fois ouvert.

PRÉLÈVEMENTS DES ÉCHANTILLONS

Utiliser tout au long du prélèvement du plastique ou du verre siliconé. Mélanger 9 volumes de sang et 1 volume de citrate de sodium à 3,2% ou 3,8%. Séparer le plasma après centrifugation à 1500 x g pendant 15 minutes. Conserver le plasma entre $^{+}$2 –$^{+}$8°C ou $^{+}$18 –$^{+}$24°C. L'analyse doit être terminée dans les 4 heures suivant le prélèvement de l'échantillon; sinon, il est possible de congeler le plasma 2 semaines à -20°C ou 6 mois à -70°C. Décongeler rapidement à $^{+}$37°C avant de réaliser l'analyse. Ne pas laisser à $^{+}$37°C plus de 5 minutes[3].

PROCÉDURE

Consulter le manuel d'utilisation de l'instrument approprié pour obtenir des instructions détaillées ou contacter Helena Biosciences Europe pour obtenir des notes d'application spécifiques à l'instrument.

INTERPRÉTATION DES RÉSULTATS

Le taux prévu de fibrinogène chez un adulte sain est de 150–350 mg/dL (1,5–3,5 g/L)[4,5].

LIMITES

Des taux d'héparine >0,6 unités/mL et de produits de dégradation fibrinolytique >100 mg/mL peuvent donner une quantification du fibrinogène erronément basse. Si les valeurs de l'échantillon patient se situent hors des valeurs de la courbe d'étalonnage, réaliser à nouveau l'analyse en utilisant la dilution appropriée pour les amener dans la plage de l'étalon.

CONTRÔLE QUALITÉ

Chaque laboratoire doit établir un programme de contrôle qualité. Les plasmas de contrôle, normaux et anormaux, doivent être testés avant chaque lot d'échantillons patients afin de s'assurer que l'instrument et l'opérateur offrent des performances satisfaisantes. Si les contrôles ne donnent pas les résultats prévus, les résultats du patient doivent être considérés comme non valables. Helena Biosciences Europe distribue les contrôles suivants à utiliser avec ce produit:

REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A
REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA

VALEURS DE RÉFÉRENCE

Les valeurs de référence peuvent varier d'un laboratoire à l'autre suivant les techniques et les systèmes utilisés. C'est pour cette raison qu'il appartient à chaque laboratoire de déterminer sa propre plage normale.

PERFORMANCES

Helena Biosciences Europe ou ses représentants ont déterminé à titre indicatif les performances suivantes. Chaque laboratoire doit établir ses propres données de performance. Le dosage du fibrinogène est conçu pour donner un étalonnage linéaire sur la plage 1,5 – 6,5 g/L.

Reproductibilité

Précision intra-série			Précision inter-séries		
Fibrinogène (g/L)	***n***	***CV (%)***	***Fibrinogène (g/L)***	***n***	***CV (%)***
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

RÉFÉRENCES

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al.* (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology,* **38**(6):196-201

Clauss Fibrinogen 50
Anleitung — de

ANWENDUNGSBEREICH

Für die quantitative Bestimmung von Fibrinogen nach der Methode nach Clauss im menschlichen Citratplasma auf den Helena Biosciences Europe AC-4, C-1, C-2, C-4 -Gerinnungssystemen.

Das Clauss Fibrinogen 50 dient der quantitativen Bestimmung von Fibrinogen im Humanplasma. Clauss[1] entwickelte zur quantitativen Bestimmung von Fibrinogen eine einfache Methode, bei der die Gerinnungszeit von verdünntem Plasma nach Zugabe von Thrombin gemessen wird (>30 NIH Einheiten/mL). Diese Gerinnungszeit ist der Fibrinogen-Konzentration direkt proportional. Das Fibrinogen kann durch Entzündung, Schwangerschaft oder Einnahme von oralen Verhütungsmitteln erhöht sein[2]. Vermindert wird es durch Lebererkrankung und Verbrauchskoagulopathie. Angeborene Mängelzustände sind insbesondere Afibrinogenämie (kein nachweisbares Fibrinogen), Hypofibrinogenämie (<1 mg/mL) und Dysfibrinogenämie (abnormales Fibrinogenmolekül).

WARNHINWEISE UND VORSICHTSMASSNAHMEN

Die Reagenzien dieses Kits sind nur zur *in vitro* Diagnostik bestimmt - NICHT EINNEHMEN. Beim Umgang mit den Kit-Komponenten ist das Tragen von Handschuhen erforderlich. Siehe die Sicherheitsdatenblätter mit Gefahrenhinweisen und Sicherheitsvorschlägen sowie Informationen zur Entsorgung. Die Plasmaprodukte sind mit negativem Befund auf Hepatitis B Antigen (HBsAg), HIV-1 und HIV-2 Antikörper und HCV-Antikörper getestet worden (wenn nicht auf Kit-Verpackung oder Fläschchen anders bezeichnet). Sie sollten trotzdem mit derselben Vorsicht wie humane Plasmaproben behandelt werden.

INHALT

Komponente	Inhalt	Beschreibung	Vorbereitung
Thrombin: 50 NIH/mL	5 x 4 mL (REF 5556) 5 x 2 mL (REF 5556H)	Jedes Fläschchen enthält ca. 200 (REF 5556) / 100 (REF 5556H) Einheiten Rinder-Thrombin mit Stabilisatoren.	Jedes Fläschchen mit: 4 mL (REF 5556) 2 mL (REF 5556H) destilliertes Wasser. Kontamination beim Pipettieren vermeiden. Leicht schwenken und 15 Minuten stehen lassen. Vor Gebrauch gut mischen. Nicht schütteln.
Fibrinogen Calibrator	2 x 1 mL (REF 5556) 1 x 1 mL (REF 5556H)	Jedes Fläschchen enthält 1 mL lyophilisiertes normales Humanplasma mit bekanntem Fibrinogen-Gehal.	Jedes Fläschchen mit genau 1,0 mL destilliertem Wasser rekonstituieren. Leicht schwenken und 10 minuten stehen lassen. Vor Gebrauch leicht mischen. Nicht schütteln.
Owren's Buffer	2 x 25 mL (REF 5556) 1 x 25 mL (REF 5556H)	Jede Flasche enthält 25 mL Puffer aus Barbital- und Natriumchlorid mit Natriumazid als Konservierungsmittel.	Der Puffer ist gebrauchsfertig verpackt.
Jedes Kit enthält eine Gebrauchsanweisung.			
Jedes Kit enthält chargenspezifischen Referenzwerten.			

NICHT MITGELIEFERTES, ABER BENÖTIGTES MATERIAL

Zur Bedienung siehe Bedienungsanleitung des Geräts und/oder Anwenderhinweise. Die Reagenzien dieses Kits sind auch einzeln erhältlich:

REF 5374	Clauss Fibrinogen (Thrombin only)
REF 5378	Clauss Fibrinogen (Thrombin only)
REF 5379	Fibrinogen Calibrator
REF 5375	Owren's Buffer

LAGERUNG UND HALTBARKEIT

Ungeöffnete Fläschchen sind unter den auf Verpackung oder Fläschchen angegebenen Lagerbedingungen bis zum aufgedruckten Verfallsdatum stabil.

Thrombin: 50 NIH/mL	Nach Rekonstitution ist das Reagenz 8 Stunden bei Raumtemperatur, 1 Woche bei $^{+}$2 –$^{+}$8°C stabil oder 1 monate bei -20°C stabil.
Fibrinogen Calibrator	Rekonstituiert ist das Reagenz bei einer Temperatur von $^{+}$2 –$^{+}$8°C für 4 Stunden stabil.
Owren's Buffer	Nach dem Öffnen bei $^{+}$2 –$^{+}$8°C lagern.

PROBENENTNAHME UND VORBEREITUNG

Nur Plastik oder Silikonglas verwenden. Blut (9 Teile) sollte in 3,2% oder 3,8% Natriumcitrat als Antikoagulanz (1 Teil) entnommen werden. 15 Minuten bei 1500 g zentrifugieren und Plasma abpipettieren. Plasma bei $^{+}$2 –$^{+}$8 °C oder $^{+}$18 –$^{+}$24°C lagern. Plasma sollte innerhalb von 4 Stunden verarbeitet oder tief gefroren bei -20°C für 2 Wochen oder -70°C für 6 Monat gelagert werden. Vor dem Testen schnell bei $^{+}$37°C auftauen. Nicht länger als 5 Minuten bei $^{+}$37°C belassen[3].

VERFAHREN

Siehe die Bedienungsanleitung des entsprechenden Geräts für genaue Anweisungen oder wenden Sie sich an Helena Biosciences Europe für spezielle anwendungstechnische Hinweise.

AUSWERTUNG DER ERGEBNISSE

Fibrinogen-Normalwerte bei gesunden Erwachsenen sind 150-350 mg/dL (1,5-3,5 g/L)[4,5].

EINSCHRÄNKUNGEN

Heparinwerte >0,6 Einheiten/mL und Fibrinolyse-Abbauprodukte >100 mg/mL können falsch niedrige Fibrinogen-Mengen ergeben. Liegen bei Patientenproben die Werte außerhalb der Standardkurve, die Proben erneut mit verdünntem Plasma testen, um die Werte in den Bereich der Standardkurve zu bringen.

QUALITÄTSKONTROLLE

Jedes Labor muss für eine eigene Qualitätskontrolle sorgen. Vor jeder Testreihe mit Patientenproben müssen normale und pathologische Kontrollplasmen getestet werden, um eine zufrieden stellende Geräteleistung und Bedienung zu gewährleisten. Liegen die Kontrollen außerhalb des Normbereichs, sind die Patientenergebnisse nicht zu verwenden. In Verbindung mit diesem Produkt bietet Helena Biosciences Europe die folgenden Kontrollen an:

REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A
REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA

REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seinen eigenen Normalwertbereich erstellen.

LEISTUNGSEIGENSCHAFTEN

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag als Richtlinien ermittelt: Jede Labor muss seine eigenen Werte ermitteln.
Der Fibrinogen-Test ist so konzipiert, dass sich eine lineare Kalibration von 1,5 – 6,5 g/L ergibt.

Reproduzierbarkeit

Intra-assay-Präzision			Inter-assay-Präzision		
Fibrinogen (g/L)	***n***	***CV (%)***	***Fibrinogen (g/L)***	***n***	***CV (%)***
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

REFERENZEN

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al.* (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology,* **38**(6):196-201

Clauss Fibrinogen 50
Istruzioni per l'uso

it

USO PREVISTO

Determinazione quantitativa del fibrinogeno secondo il metodo di Clauss presente nel plasma citrato umano su sistemi di coagulazione Helena Biosciences Europe AC-4, C-1, C-2, C-4.

Il kit di Fibrinogeno Clauss 50 è stato formulato per la determinazione quantitativa del fibrinogeno in plasma umano. Clauss[1] ha messo a punto un semplice metodo per la determinazione quantitativa del fibrinogeno misurando il tempo di coagulazione del plasma diluito in seguito all'aggiunta di Thrombin (>30 NIH unità/mL). Questo tempo di coagulazione è proporzionale alla concentrazione di fibrinogeno. I livelli di fibrinogeno possono aumentare in seguito ad infiammazione, gravidanza o impiego di contraccettivi orali[2]. Livelli ridotti di fibrinogeno sono riscontrabili in alcuni stati, come ad esempio le patologie epatiche e la DIC. Tra le carenze congenite rientrano l'afibrinogenemia (assenza di fibrinogeno rilevabile), l'ipofibrinogenemia (<1 mg/mL) e la disfibrinogenemia (molecola di fibrinogeno anomala).

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare guanti protettivi durante l'uso dei componenti del kit. Fare riferimento alle istruzioni del prodotto per avvertenze su rischi e sicurezza ed informazioni sullo smaltimento dei componenti. I prodotti plasmatici sono stati esaminati dando esito negativo (salvo diversamente indicato sulla confezione del kit o sul flacone) relativamente alla presenza dell'antigene dell'epatite B (HbsAg), dell'anticorpo anti-HIV 1 e 2 e dell'anticorpo anti-HCV; questi prodotti devono tuttavia essere manipolati con le stesse misure precauzionali adottate per un campione di plasma umano.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
Thrombin: 50 NIH/mL	5 x 4 mL (REF 5556) 5 x 2 mL (REF 5556H)	Ogni flacone contiene approssimativamente 200 (REF 5556) / 100 (REF 5556H) unità di Thrombin bovina con stabilizzatori.	Ricostituire ogni flacone con: 4 mL (REF 5556) 2 mL (REF 5556H) di acqua distillate. Durante il pipettaggio, prestare attenzione ad evitare la contaminazione. Agitare delicatamente e lasciare riposare per 15 minuti. Miscelare bene immediatamente prima dell'uso. Non scuotere.
Fibrinogen Calibrator	2 x 1 mL (REF 5556) 1 x 1 mL (REF 5556H)	Ogni flacone contiene 1 mL di plasma umano normale liofilizzato dosato per i livelli di fibrinogeno.	Ricostituire ogni flacone con esattamente 1,0 mL di acqua distillata. Agitare delicatamente e lasciare riposare per 10 minuti. Miscelare delicatamente prima dell'uso. Non scuotere.
Owren's Buffer	2 x 25 mL (REF 5556) 1 x 25 mL (REF 5556H)	Ogni flacone contiene 25 mL di tampone contenente barbital e sodio cloruro con sodio azide come conservante.	Il tampone è pronto all'uso così come viene fornito.

Ogni kit contiene un Istruzioni per l'uso.

Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

Fare riferimento al manuale utente dello strumento e/o alla nota applicativa per conoscere le istruzioni specifiche. Ireagenti contenuti in questo kit sono disponibili anche come materiale separato:

REF 5374	Clauss Fibrinogen (Thrombin only)
REF 5378	Clauss Fibrinogen (Thrombin only)
REF 5379	Fibrinogen Calibrator
REF 5375	Owren's Buffer

CONSERVAZIONE E STABILITÀ

I flaconi non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sul flacone o sull'etichetta del kit.

Thrombin: 50 NIH/mL	Dopo la ricostituzione, il reagente è stabile per 8 ore a temperatura ambiente, 1 settimana a $^{+}2$ –$^{+}8$°C o per 1 mesi a -20°C.
Fibrinogen Calibrator	Dopo la ricostituzione, il reagente è stabile per 4 ore a $^{+}2$ –$^{+}8$°C.
Owren's Buffer	Una volta aperto, conservare a $^{+}2$ –$^{+}8$°C.

RACCOLTA DEI CAMPIONI E PREPARAZIONE

Nel corso dell'intera procedura è necessario utilizzare plastica o vetro siliconizzato. Il sangue (9 parti) deve essere raccolto in sodio citrato al 3,2% o al 3,8% come anticoagulante (1 parte). Separare il plasma in seguito a centrifugazione a 1500 x g per 15 minuti. Il plasma deve essere conservato a $^{+}2$ –$^{+}8$°C o $^{+}18$ –$^{+}24$°C. I test devono essere completati entro 4 ore dalla raccolta dei campioni; in alternativa, il plasma può essere conservato congelato a -20°C per 2 settimane o a -70°C per 6 mese. Decongelare rapidamente a $^{+}37$°C prima di eseguire i test. Non conservare a $^{+}37$°C per oltre 5 minuti[3].

PROCEDURA

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europe per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

Nei soggetti adulti sani i valori previsti per il fibrinogeno sono di 150-350 mg/dL (1,5-3,5 g/L)[4,5].

LIMITAZIONI

I livelli di eparina >0,6 unità/mL e i prodotti fibrinolitici di degradazione >100 mg/mL possono causare una quantificazione del fibrinogeno falsamente bassa. Se i valori fuoriescono dai valori della curva standard per i campioni dei pazienti, ripetere il dosaggio utilizzando una diluizione appropriata per portare i valori all'interno del range standard.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi. Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:

REF 5301	Speciality Assayed Control N
REF 5302	Speciality Assayed Control A
REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA

VALORI DI RIFERIMENTO

I valori di riferimento possono variare da un laboratorio all'altro in funzione delle tecniche e dei sistemi in uso. Per tale motivo ciascun laboratorio dovrà elaborare un proprio range normale.

CARATTERISTICHE PRESTAZIONALI

Le caratteristiche prestazionali sotto riportate sono state determinate da Helena Biosciences Europe o dai propri rappresentanti a titolo di linee guida. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali. Il dosaggio del fibrinogeno è stato studiato per fornire calibrazione lineare compresa tra 1,5-6,5 g/L.

Riproducibilità

Precisione intra-dosaggio			Precisione tra i dosaggi		
Fibrinogeno (g/L)	***n***	***CV (%)***	***Fibrinogeno (g/L)***	***n***	***CV (%)***
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

RIFERIMENTI

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al.* (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology,* **38**(6):196-201

Clauss Fibrinogen 50
Instrucciones de uso

es

USO PREVISTO

La determinación cuantitativa de fibrinógeno basada en el método Clauss del plasma humano citrado en sistemas de coagulación Helena Biosciences Europe AC-4, C-1, C-2, C-4.

El Kit de Fibrinógeno de Clauss 50 está previsto para la determinación cuantitativa del fibrinógeno en el plasma humano. Clauss[1] desarrolló un método simple para la determinación cuantitativa de fibrinógeno midiendo el tiempo de coagulación del plasma diluido después de la adición de Thrombin (>30 unidades NIH/mL). Este tiempo de coagulación es proporcional a la concentración de fibrinógeno. Los niveles de fibrinógeno pueden aumentar como consecuencia de inflamación, embarazo o uso de anticonceptivos orales[2]. Pueden encontrarse niveles disminuidos en determinados estados como la hepatopatía y la CID. Entre las deficiencias congénitas están la afibrinogenemia (sin fibrinógeno detectable), la hipofibrinogenemia (<1 mg/mL) y la disfibrinogenemia (molécula de fibrinógeno anormal).

ADVERTENCIAS Y PRECAUCIONES

Los reactivos contenidos en este kit son sólo para uso diagnóstico – NO SE DEBEN INGERIR. Usar guantes para manejar todos los componentes del kit. Consultar la hoja con los datos de seguridad del producto acerca de los riesgos, avisos de seguridad y consejos para su eliminación. Los productos plasmáticos se han sometido a pruebas y han resultado negativos (a menos que se indique otra cosa en la caja del kit o en el vial) para la presencia de antígeno de la hepatitis B (HbsAg), anticuerpos de VIH 1 y 2 y anticuerpo del VHC; sin embargo, deben manipularse con las mismas precauciones que una muestra de plasma humano.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
Thrombin: 50 NIH/mL	5 x 4 mL (REF 5556) 5 x 2 mL (REF 5556H)	Cada vial contiene aproximadamente 200 (REF 5556) / 100 (REF 5556H) unidades de trombina bovina con estabilizadores.	Reconstituya cada vial con: 4 mL (REF 5556) 2 mL (REF 5556H) de agua purificada. Tener cuidado al pipetear para evitar la contaminación. Agitar suavemente y permitir que repose durante 15 minutos. Mezclar bien inmediatamente antes de usar. No agitar.
Fibrinogen Calibrator	2 x 1 mL (REF 5556) 1 x 1 mL (REF 5556H)	Cada vial contiene 1,0 mL de plasma humano normal liofilizado estudiado en cuanto a niveles de fibrinógeno.	Reconstituir cada vial con exactamente 1,0 mL de agua destilada. Agitar suavemente y permitir que repose durante 10 minutos. Mezclar suavemente antes de su uso. No agitar.
Owren's Buffer	2 x 25 mL (REF 5556) 1 x 25 mL (REF 5556H)	Cada frasco contiene 25 mL de tampón con barbital y cloruro sódico con azida sódica como conservante.	El tampón viene envasado listo para usar.

Cada kit contiene instrucciones de uso.

Cada kit contiene valores de referencia específicos insertados del lote.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

Consúltese el Manual del Operador del Instrumento y/o la nota de aplicación para instrucciones adecuadas. Los reactivos contenidos en este kit están también disponibles como artículos separados:

REF 5374	Clauss Fibrinogen (Thrombin only)
REF 5378	Clauss Fibrinogen (Thrombin only)
REF 5379	Fibrinogen Calibrator
REF 5375	Owren's Buffer

ALMACENAJE Y ESTABILIDAD

Los viales no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit.

Thrombin: 50 NIH/mL	El reactivo reconstituido permanece estable durante 8 horas a temperatura ambiente, 1 semana a $^{+}2$ –$^{+}8$°C o 1 meses a -20°C.
Fibrinogen Calibrator	Una vez reconstituido, el reactivo permanece estable durante 4 horas a $^{+}2$ –$^{+}8$°C.
Owren's Buffer	Conservar a $^{+}2$ –$^{+}8$°C una vez abierto.

RECOGIDA Y PREPARACIÓN DE MUESTRAS

Debe usarse siempre plástico o vidrio siliconizado. Debe recogerse sangre (9 partes) en el anticoagulante citrato sódico al 3,2% o al 3,8% (1 parte). Separar el plasma después de la centrifugación a 1500 x g durante 15 minutos. El plasma debe conservarse a $^{+}2$ –$^{+}8$ºC o $^{+}18$ –$^{+}24$°C. Las pruebas deberían terminarse en 4 horas desde la recogida de las muestras o el plasma puede conservarse congelado a -20°C durante 2 semanas o ¯70°C durante 6 mes. Descongelar rápidamente a $^{+}37$°C antes de realizar la prueba. No conservar a $^{+}37$°C durante más de 5 minutos[3].

PROCEDIMIENTO

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE RESULTADOS

Los valores esperados para el fibrinógeno en adultos sanos son de 150-350 mg/dL (1,5-3,5 g/L)[4,5].

LIMITACIONES

Los niveles de heparina >0,6 unidades/mL y los productos de degradación fibrinolíticos >100 mg/mL pueden producir una cuantificación falsamente baja del fibrinógeno. Si los valores caen fuera de los valores de la curva estándar para las muestras de pacientes, vuelva a realizar la valoración usando una dilución adecuada para llevar los valores al intervalo estándar.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los controles normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos. Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:

REF 5301	Speciality Assay Control N
REF 5302	Speciality Assay Control A
REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer su propio intervalo normal.

CARACTERÍSTICAS FUNCIONALES

Helena Biosciences Europeo sus representantes han determinado las siguientes características de rendimiento como directriz. Cada laboratorio debe establecer sus propios datos de rendimiento. La valoración del fibrinógeno está diseñada para dar una calibración lineal de 1,5 a 6,5 g/L.

Reproducibilidad

Precisión intra-ensayo			Precisión inter-ensayo		
Fibrinógeno (g/L)	***n***	***CV (%)***	***Fibrinógeno (g/L)***	***n***	***CV (%)***
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

REFERENCIAS

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al.* (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology,* **38**(6):196-201

Тест-система "Определение фибриногена методом Клаусса 50"
инструкция

ru

ПРИМЕНЕНИЕ

Тест-система "Определение фибриногена методом Клаусса 50" предназначена для проведения количественного определения фибриногена по Клауссу в плазме крови человека на коагулометрах производства компании Хелена C-1/2/4/AC-4.

Тест-система "Определение фибриногена методом Клаусса 50" предназначена для проведения количественного определения фибриногена по Клауссу в плазме крови человека на коагулометрах. Метод Клаусса[1] – простой метод количественного определения фибриногена, основанный на измерении времени образования сгустка. Метод проводится в разведенной плазме после добавления тромбинового реагента (> 30 МЕ/мл). Время образования сгустка пропорционально концентрации фибриногена. Уровень фибриногена может увеличиваться при воспалении, беременности или при приеме пероральных контрацептивов[2]. Низкие значения могут наблюдаться при заболеваниях печени и ДВС. Изменение содержания фибриногена в плазме помогает диагностике врожденных дефицитных состояний, включая афибриногенемию (полное отсутствие фибриногена), гипофибриногенемию (концентрация фибриногена менее 1 мг/мл) и дисфибриногенемию (структурные нарушения в молекуле фибриногена).

ПРЕДУПРЕЖДЕНИЯ И ПРЕДОСТОРОЖНОСТИ

Реактивы, содержащиеся в наборе, предназначены только для *in-vitro* диагностики. При работе с любым из компонентов набора применяйте соответствующую защитную одежду (одноразовые резиновые или пластиковые перчатки и т.д.). Ознакомьтесь с инструкцией по мерам предосторожности. Тестирование контрольной плазмы (либо реагента) на содержание антигена вируса гепатита B (HBsAg), антител к HIV I и II антител и HCV дало отрицательный результат (за исключением, если последнее не указано на упаковке или флаконе), тем не менее, при работе с ней/ним следует соблюдать такую же осторожность, как и при работе с образцами плазмы крови человека.

СОСТАВ РЕАГЕНТОВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Тромбиновый Реагент: 50 МЕ/мл	5 x 4 мл (Кат. № 5556) 5 x 2 мл (Кат. № 5556H)	содержит 200 единиц (Кат. № 5556) / 100 единиц (Кат. № 5556H) бычьего тромбина со стабилизаторами.	Внести во флакон: 4.0 мл (Кат. № 5556) или 2.0 мл (Кат. № 5556H) дистиллированной (деионизированной воды). Осторожно перемешать и оставить при комнатной температуре в течение 15 минут. Перед использованием еще раз перемешать. Не встряхивать.
Калибратор Фибриногена	2 x 1 мл (Кат. № 5556) 1 x 1 мл (Кат. № 5556H)	Содержит 1.0 мл лиофилизированной нормальной плазмы человека, аттестованной по уровню фибриногена.	Внести во флакон 1.0 мл дистиллированной или деионизированной воды. Осторожно перемешать и оставить при комнатной температуре в течение 10 минут. Перед использованием еще раз перемешать. Не встряхивать.
Буфер Оуренса	2 x 25 мл (Кат. № 5556) 1 x 25 мл (Кат. № 5556H)	Флакон содержит 25.0 мл готового к использованию буфера, содержащего натрия хлорид и натрия азид в качестве стабилизатора	Дополнительные разведения не требуются.

Каждый набор содержит инструкцию по применению.

Паспорт с референсными значениями.

ТРЕБУЕМЫЕ, НО НЕ ПОСТАВЛЯЕМЫЕ МАТЕРИАЛЫ

Адаптации реагентов к различным приборам доступны по запросу у официальных дистрибьюторов и компании Хелена. Реагенты, входящие в набор могут быть заказаны отдельно:

Кат. № 5374	Тест-система "Фибриноген по Клауссу (только тромбиновый реагент)"
Кат. № 5378	Тест-система "Фибриноген по Клауссу (только тромбиновый реагент)"
Кат. № 5379	Калибратор фибриногена
Кат. № 5375	Тестовый реагент "Буфер Оуренса"

ХРАНЕНИЕ И СТАБИЛЬНОСТЬ

Невскрытые флаконы хранятся до истечения срока годности в условиях, указанных на упаковке или этикетке.

Тромбиновый Реагент: 50 МЕ/мл	После растворения, тромбиновый реагент стабилен в течение 7 дней при $^{+}2$ –$^{+}8$°C, 8 часов на борту анализатора при $^{+}15$ –$^{+}30$°C и 1 месяц при -20°C
Калибратор Фибриногена	После растворения, калибратор стабилен в течение 4 часов при $^{+}2$ –$^{+}8$°C
Буфер Оуренса	Вскрытый флакон с буфером следует хранить при $^{+}2$ –$^{+}8$°C

СБОР И ПРИГОТОВЛЕНИЕ ОБРАЗЦОВ

Для работы следует использовать только пластиковые или силиконированные стеклянные пробирки. Кровь забирается в пробирку с цитратным антикоагулянтом (3,2% или 3,8% цитрат натрия) в соотношении 9 + 1. После центрифугирования при 1500 g, в течение 15 минут (использование других параметров должно проверяться лабораторией), полученную плазму необходимо отделить от форменных элементов крови. Плазму следует хранить при температуре $^{+}2$ –$^{+}8$°C или $^{+}18$ –$^{+}24$°C. Тестирование должно быть проведено в течение 4 часов после забора образцов, либо плазму можно однократно заморозить и хранить при температуре -20°C в течение 2 недель или при -70°C в течение 6 месяцев. Перед проведением исследования плазму следует быстро разморозить при $^{+}37$°C. Не держать плазму при $^{+}37$°C более 5 минут[3].

ПРОЦЕДУРА ВЫПОЛНЕНИЯ АНАЛИЗА

Для получения более подробной информации обратитесь к инструкции на автоматический или полуавтоматический коагулометр.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Средний уровень Фибриногена в популяции практически здоровых людей находится между 150-350 мг/дл (1.5-3.5 г/л)[4,5].

ОГРАНИЧЕНИЯ

На низко ложные результаты концентрации фибриногена, полученные на коагулометре, может влиять гепарин в концентрации >0.6 Ед/мл и ПДФ в концентрации >100 мг/мл. Если значения образцов пациентов выпадают за график стандартной кривой, то требуется дальнейшее разведение образца, чтобы значение попадали в линейный диапазон от 1,0 до 6,5 г/л.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными. омпания Хелена рекомендует следующие контрольные материалы:

Кат. № 5301	Контроль качества специальные тесты, норма
Кат. № 5302	Контроль качества специальные тесты, патология
Кат. № 5186	Контроль качества, норма
Кат. № 5187	Контроль качества, умеренно выраженная патология
Кат. № 5183	Контроль качества, высокая патология

РЕФЕРЕНСНЫЕ ЗНАЧЕНИЯ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и коагулометров. По этой причине каждая лаборатория должна установить свои собственные значения.

АНАЛИТИЧЕСКИЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики. При использовании ручного метода были определены следующие коэффициенты вариации (CV) и линейность в диапазоне от 1,0 до 6,5 г/л (без дополнительных разведений плазмы).

Воспроизводимость

в пределах аналитической серии			между разными аналитическими сериями		
Фибриноген (г/л)	***n***	***CV (%)***	***Фибриноген (г/л)***	***n***	***CV (%)***
1.24	5	4.88	1.02	10	6.17
3.01	5	3.58	3.62	10	3.75

СПИСОК ЛИТЕРАТУРЫ

1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur bestimmung des Fibrinogens, *Acta Haematol*, **17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al.* (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology,* **38**(6):196-201

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#001/35-2014

Wir / *We*

TECO Medical Instruments Production and Trading GmbH
Name des Herstellers / Manufacturer's *name*
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass die Produkte – IVD-Blutgerinnungsmessgeräte,
declare under our own responsibility, that the products – IVD Coagulation analyzers

Coatron X Eco, Pro, Top

Bezeichnung, Typ oder Modellname / *name, type or model*

allen anwendbaren Anforderungen der folgenden Richtlinien entsprechen:	*meet all applicable requirements of:*
1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"	*1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"*
2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit	*2. Directive 2014/30/EU on electromagnetic Compatibility*
3. Richtlinie 2011/65/EU RoHS II	*3. Directive 2011/65/EU RoHS II*
Das QM-System des Herstellers ist zertifiziert nach:	*The QM-system of the manufacturer is certified for:*
EN ISO 13485:2016	***EN ISO 13485:2016***
Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.	*This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of properties.*
Konformitätsbewertungsverfahren:	*Conformity assessment procedure:*
Gemäß Anhang III der Richtlinie 98/79/EG	*According to Annex III of Directive 98/79/EC*

Ort und Datum der Unterzeichnung: Neufahrn, 27.03.2019
Place and date of issue: Neufahrn, March 27, 2019

Christian Hötzl
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ELITechGroup
EMPOWERING IVD

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages) , conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

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Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	53250
CREATININE PAP SL	CRSL-0630/0250	
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPSL-0850	53301
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP	GPSL-M690	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	53985
TOTAL PROTEIN ENVOY	PROB-0850	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	53587
UREA ENVOY	URSL-0850	
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	53583
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE	AMSL-M430	52940
AMYLASE ENVOY	AMSL-0850	
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	52954
AST ENVOY	ASVD-0850	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	53003
CK NAC SL	CKSL-0410/0430/0230	
GAMMA-GT	GISL-M230	53027
GAMMA-GT PLUS SL	GISL-0400/0420/0250	
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH IFCC	LLSL-M230	
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	53108
LIPASE ENVOY	LPSL-0850	
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-élements / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600/M230	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600/M430	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	53359
CHOLESTEROL ENVOY	CHSL-0850	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250/M330	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES	TGML-M690	53460
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	

Vla

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

ELICAL 2

CALI
CALI-0550 : 4 x 3 mL

FTCE-CALI2-5-v5 (07/2020)

Français - FR

☛USAGE PRÉVU
Ce dispositif de diagnostic *in vitro* est destiné à la calibration des tests quantitatifs ELITech Clinical Systems listés dans la fiche de valeurs.
Ce dispositif de diagnostic *in vitro* est uniquement destiné aux professionnels.

☛COMPOSITION
- Produit sous forme lyophilisée préparé à partir de sérum humain contenant des additifs chimiques et biologiques.
- Azide de sodium < 0.1 % (p/p)
- Les concentrations pour chaque analyte à doser sont spécifiques à chaque lot.

☛MATÉRIELS REQUIS MAIS NON FOURNIS
- Réactifs ELITech Clinical Systems listés dans la fiche de valeurs.
- Equipement général de laboratoire.

☛TRACABILITE
La traçabilité est indiquée dans la fiche de valeurs incluse dans le coffret.

☛PRÉCAUTIONS D'EMPLOI ET MISES EN GARDE
- Chaque unité de sang humain utilisée pour la fabrication de ces produits a été testée et trouvée négative/non-réactive pour la présence d'HBsAg, HCV et HIV1/2. Les méthodes utilisées étaient approuvées par la FDA ou autorisées en conformité à la Directive Européenne 98/79 / CE, Annexe II, liste A. Cependant le risque d'infection ne pouvant être exclu avec certitude par aucune méthode, ces produits doivent être manipulés comme étant potentiellement infectieux. En cas d'exposition, suivre les directives des autorités sanitaires compétentes.
- Prendre des précautions lors de la manipulation de flacons de verre brisés, car les bords tranchants peuvent blesser l'utilisateur.
- Ces produits contiennent de l'azide de sodium qui peut réagir avec le plomb ou le cuivre et former des azides métalliques potentiellement explosifs. Lors de l'élimination de ces réactifs toujours rincer abondamment avec de l'eau pour éviter l'accumulation d'azides.
- Respecter les précautions d'usage et les bonnes pratiques de laboratoire.
- Utiliser du matériel de laboratoire propre ou à usage unique afin d'éviter toute contamination.
- Consulter la fiche de données de sécurité (FDS) pour une manipulation appropriée.

☛TRAITEMENT DES DÉCHETS
L'élimination de tous les déchets doit être effectuée conformément aux exigences réglementaires locales, d'état et fédérales (veuillez-vous référer à la fiche de données de sécurité (FDS)).

☛PRÉPARATION
- Ouvrir avec précaution le flacon en évitant la perte de poudre lyophilisée.
- Ajouter **précisément 3 mL d'eau distillée ou désionisée**.
- Reboucher le flacon avec soin et dissoudre le contenu complètement dans les 30 minutes en remuant délicatement le flacon et en évitant la formation de mousse.

☛DÉTÉRIORATION DU PRODUIT
- Le produit peut présenter un aspect légèrement trouble après reconstitution. Cela n'a aucun effet sur les performances du produit. Toute présence de particules serait le signe d'une détérioration.
- Ne pas utiliser le produit s'il y a des signes évidents de détérioration biologique ou chimique (ex : particules après reconstitution).
- Un flacon endommagé peut avoir un impact sur les performances du produit. Ne pas utiliser le produit si les flacons présentent des signes physiques de détérioration (par exemple, fuite).

☛STABILITÉ
Avant reconstitution :
- Stocker à 2-8 °C et à l'abri de la lumière.
- Ne pas utiliser après la date d'expiration indiquée sur l'étiquette du flacon.

Après reconstitution :
- Ces produits doivent être immédiatement et correctement refermés afin d'éviter toute contamination ou évaporation.

- Stabilité des constituants :
Entre 15 et 25 °C : 8 heures
Entre 2 et 8 °C : 2 jours
Entre -25 et -15 °C : 4 semaines (ne congeler qu'une seule fois)

Exceptions :
- Stabilité de la bilirubine totale (à conserver à l'abri de la lumière) :
Entre 15 et 25 °C : 6 heures
Entre 2 et 8 °C : 1 jour
Entre -25 et -15 °C : 2 semaines (ne congeler qu'une seule fois)
- Stabilité de la bilirubine directe (à conserver à l'abri de la lumière) :
Entre 15 et 25 °C : 3 heures
Entre 2 et 8 °C : 8 heures
Entre -25 et -15 °C : 2 semaines (ne congeler qu'une seule fois)

***Note** : Conserver les flacons bien fermés et à l'abri de la lumière.*

☛PROCÉDURE
Pour utiliser ELICAL 2, suivre la procédure décrite dans la fiche technique du réactif ELITech Clinical Systems utilisé.

☛LIMITATIONS
L'utilisation de ELICAL 2 a été validée avec les systèmes ELITech (Automates et réactifs listés dans la fiche de valeurs).
L'utilisation sur un autre système doit être validée par le laboratoire.

☛VALEURS
Les concentrations sont indiquées dans la fiche de valeurs incluse dans le coffret.
Pour les utilisateurs d'automates Selectra permettant l'import de tests, de calibrants et de contrôles, utiliser le code barre correspondant, disponible sur la fiche de valeurs.

☛DECLARATION DES INCIDENTS GRAVES
Veuillez notifier au fabricant (par l'intermédiaire de votre distributeur) et à l'autorité compétente de l'Etat membre de l'union européenne dans lequel l'utilisateur et/ou le patient est établi, les cas d'incident grave survenu en lien avec le dispositif.
Pour les autres juridictions, la déclaration d'incident grave doit être effectuée conformément aux exigences réglementaires locales, d'état et fédérales.
En signalant les incidents graves, vous contribuez à fournir davantage d'informations sur la sécurité des dispositifs médicaux de diagnostic *in vitro*.

☛TECHNICAL ASSISTANCE
Contacter votre distributeur local ou ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

English - EN

☛INTENDED USE
This *in vitro* diagnostic device is intended for the calibration of ELITech Clinical Systems quantitative tests listed in the value sheet.
This *in vitro* diagnostic device is for professional use only.

☛COMPOSITION
- Lyophilized product prepared from human serum spiked with chemical and biological additives.
- Sodium azide < 0.1 % (w/w)
- Concentrations for each analyte to test are lot-specific.

☛MATERIALS REQUIRED BUT NOT PROVIDED
- ELITech Clinical Systems reagents listed in the value sheet.
- General Laboratory equipment.

☛TRACEABILITY
The traceability is indicated in the value sheet enclosed in the kit.

☛PRECAUTIONS FOR USE AND WARNINGS
- Each unit of human blood used in the manufacture of these products was tested and found to be negative/non-reactive for the presence of HbsAg, HCV and HIV1/2. The methods used were FDA approved or cleared in compliance with European Directive 98/79/EC, Annex II, List A. Nevertheless, since the risk of infection cannot be fully excluded these products must be handled as potentially infectious. In case of exposure, follow the guidelines of the competent health authorities.
- Take precautions when handling broken glass vials as sharp edges can injure the user.
- These products contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- Consult Safety Data Sheet (SDS) for a proper handling.

☛WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

☛PREPARATION
- Carefully open the vial, avoiding the loss of lyophilizate.
- Add **in exactly 3 mL of distilled or deionized water**.
- Carefully close the vial and dissolve the contents completely within 30 minutes by occasional gentle stirring avoiding the formation of foam.

☛PRODUCT DETERIORATION
- The product may present a slightly hazy appearance after reconstitution. This has no effect on the performances of the product. All presence of particles would indicate deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter after reconstitution).
- Damage to the container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages).

☛STABILITY
Prior to reconstitution :
- Stored at 2-8 °C and protected from light.
- Do not use after expiration date indicated on the vial label.

After reconstitution :
- These products should be immediately and tightly capped to prevent contamination and evaporation.

- Stability of the components:
Between 15 and 25 °C : 8 hours
Between 2 and 8 °C : 2 days
Between -25 and - 15 °C : 4 weeks (when frozen once)

Exceptions:
- Stability of total bilirubin (when stored protected from light):
Between 15 and 25 °C : 6 hours
Between 2 and 8 °C : 1 day
Between -25 and -15 °C : 2 weeks (When frozen once)
- Stability of direct bilirubin (when stored protected from light):
Between 15 and 25 °C : 3 hours
Between 2 and 8 °C : 8 hours
Between -25 and -15 °C : 2 weeks (when frozen once)

***Note**: Store vials tightly capped and protected from light.*

☛PROCEDURE
To use ELICAL 2, follow the procedure described in the instructions for use of the ELITech Clinical Systems reagent used.

☛LIMITATIONS
Using ELICAL 2 has been validated with the ELITech systems (Analyzers and reagents listed in the value sheet).
Using any other system should be validated by the laboratory.

☛VALUES
The concentrations are indicated in the value sheet enclosed in the kit.
For users of Selectra instruments allowing data import for tests, calibrators and controls, use corresponding barcode, available on the value sheet.

☛DECLARATION OF SERIOUS INCIDENT
Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

☛ASSISTANCE TECHNIQUE
Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Español - ES

☛USO PREVISTO
Este dispositivo de diagnóstico *in vitro* está diseñado para la calibración de las pruebas cuantitativas ELITech Clinical Systems listadas en la hoja de valores.
Este dispositivo de diagnóstico *in vitro* esta destinado unicamente para los profesionales.

☛COMPOSICIÓN
- Producto liofilizado preparado a partir de suero humano enriquecido con aditivos químicos y biológicos.
- Azida sódica < 0.1 % (p/p)
- Las concentraciones de cada analito a analizar son específicas a cada lote.

☛MATERIALES REQUERIDOS PERO NO INCLUIDOS
- Reactivos ELITech Clinical Systems listados en la hoja de valores.
- Equipo de laboratorio de uso general.

☛TRAZABILIDAD
La trazabilidad se indica en la ficha de valores incluida en el kit.

☛PRECAUCIONES DE USO Y ADVERTENCIAS
- Cada unidad de sangre humana utilizada en la fabricación de estos productos fue analizada y resultó ser negativa / no reactiva ante la presencia de HbsAg, VHC y VIH1/2. Los métodos utilizados fueron aprobados de conformidad por la FDA y con la Directiva Europea 98/79 / CE, Anexo II, Lista A. Sin embargo, dado que el riesgo de infección no puede excluirse por completo, estos productos deben manejarse como potencialmente infecciosos. En caso de exposición, siga las indicaciones de las autoridades sanitarias competentes.
- Tenga precauciones al manipular viales de vidrio roto, ya que los bordes afilados pueden dañar al usuario.
- Los productos contienen azida sódica que puede reaccionar con el plomo o el cobre de la tubería y potencialmente formar azidas metálicas explosivas. Cuando se eliminen los reactivos, enjuague con agua abundantemente para prevenir la acumulación de azidas.
- Respetar las precauciones de uso y las buenas prácticas de laboratorio.
- Para evitar contaminaciones utilizar equipo nuevo o completamente limpio.
- Consulte la Hoja de Datos de Seguridad (SDS) para un manejo adecuado.

☛TRATAMIENTO DE LOS RESIDUOS
Todos los materiales de desecho deben eliminarse de acuerdo con los requisitos regulatorios locales, estatales y federales (diríjase a la hoja de seguridad (SDS)).

☛PREPARACIÓN
- Destapar cuidadosamente el frasco con el fin de evitar la pérdida de material liofilizado.
- Agregar **exactamente 3 mL de agua destilada o de agua desionizada.**
- Cierre cuidadosamente el vial y disuelva el contenido por completo durante 30 minutos mezclando suavemente para evitar la formación de espuma.

☛DETERIORACIÓN DEL PRODUCTO
- El producto puede presentar un aspecto ligeramente turbio después de reconstitución, esto no afecta el rendimiento del producto. La presencia de partículas es un signo de deterioro.
- No utilice el producto si este presenta signos evidentes de contaminación o deterioro (p. ej, partículas después de reconstitución).
- Un frasco dañado puede tener un impacto en el rendimiento del producto. No utilice el producto si este tiene signos físicos de deterioro (p. ej, fugas).

☛ESTABILIDAD
Antes de la reconstitución :
- Conservar a 2-8 °C y protegidos de la luz.
- No utilice después de la fecha de caducidad indicada en la etiqueta del frasco.

Después de reconstitución :
- Estos productos deben ser bien cerrados de inmediato para evitar contaminación y evaporación.

- Estabilidad de los componentes:
Entre 15 y 25 °C : 8 horas
Entre 2 y 8 °C : 2 días
Entre -25 y -15 °C : 4 semanas (no congelar más de una vez)

Excepciones:
- Estabilidad de la bilirrubina total (proteger de la luz) :
Entre 15 y 25 °C : 6 horas
Entre 2 y 8 °C : 1 día
Entre -25 y -15 °C : 2 semanas (no congelar más de una vez)
- Estabilidad de la bilirrubina directa (proteger de la luz) :
Entre 15 y 25 °C : 3 horas
Entre 2 y 8 °C : 8 horas
Entre -25 y -15 °C : 2 semanas (no congelar más de una vez)

Nota : Conservar los frascos bien cerrados y protegidos de la luz.

☛PROCEDIMIENTO
Para utilizar ELICAL 2, siga el procedimiento descrito en el inserto del reactivo ELITech Clinical Systems utilizado.

☛LIMITACIONES
El uso de ELICAL 2 ha sido validado con los sistemas ELITech (equipos y reactivos enumerados en la hoja de valores).
El uso de cualquier otro sistema debe ser validado por el laboratorio.

☛VALORES
Las concentraciones son indicadas en la ficha de valores incluida en el kit.
Para usuarios de los equipos Selectra que permiten la importación de pruebas, calibradores y controles, use el código de barras correspondiente, disponible en la hoja de valores.

☛DECLARACIÓN DE INCIDENTES GRAVES
Por favor notifique al fabricante (por medio de su distribuidor) y autoridad competente del Estado miembro de la Unión Europea en donde el usuario o paciente radique, de cualquier incidente grave que se produzca con relación al dispositivo.
Para otras jurisdicciones, la declaración de incidentes graves debe realizarse
de acuerdo con los requisitos reglamentarios locales, estatales y federales.
Reportando incidentes graves usted contribuye a proporcionar más información sobre la seguridad del dispositivo médico de diagnóstico *in vitro*.

☛ASISTENCIA TÉCNICA
Contacte a su distribuidor local o con ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Português - PT

☛UTILIZAÇÃO PREVISTA
Este dispositivo de diagnóstico *in vitro* é destinado a calibração dos testes quantitativos ELITech Clinical Systems listados na folha de valores.
Este dispositivo de diagnóstico *in vitro* é apenas para uso profissional.

☛COMPOSIÇÃO
- Produto liofilizado preparado a partir de soro humano enriquecido com aditivos químicos e biológicos.
- Azida de sódio < 0.1 % (p/p)
- As concentrações de cada analito a ser testado são específicas de cada lote.

☛MATERIAIS NECESSÁRIOS MAS NÃO FORNECIDOS
- ELITech Clinical Systems reagentes listados na folha de valores.
- Equipamento geral de laboratório.

☛RASTREABILIDADE
A rastreabilidade é indicada na folha de valores incluída no kit.

☛PRECAUÇÕES DE USO E AVISOS
- Cada unidade de sangue humano utilizada na fabricação desses produtos foi testada e se mostrou negativa / não reativa para a presença de HbsAg, HCV e HIV1 / 2. Os métodos utilizados foram aprovados e liberados pela FDA em conformidade com a Diretiva Européia 98/79 / EC, Anexo II, Lista A. No entanto, como o risco de infecção não pode ser totalmente excluído, esses produtos devem ser manuseados como potencialmente infecciosos. Em caso de exposição, siga as orientações das autoridades sanitárias competentes.
- Tome precauções ao manusear frascos de vidro quebrados, pois bordas afiadas podem ferir o usuário.
- Os produtos contém azida de sódio que pode reagir com o chumbo ou cobre das canalizações formando azidas metálicas explosivas. Ao manusear estes reagentes lave as mãos sempre com grandes quantidades de água para evitar a produção de azida.
- Respeitar as precauções de utilização e as boas práticas de laboratório.
- Utilizar material de laboratório limpo ou destinado a uma única utilização de modo a evitar qualquer contaminação.
- Consulte a ficha de dados de segurança (SDS) para obter um manuseio adequado.

☛TRATAMENTO DOS RESÍDUOS
O descarte de todo material residual deve estar de acordo com os requisitos regulamentares locais, estaduais e federais (consulte a Ficha de dados de segurança (SDS)).

☛PREPARAÇÃO
- Abrir cuidadosamente o frasco, evitando a perda de pó liofilizado.
- Acrescentar **exatamente 3 mL de água destilada ou deionizada**.
- Feche cuidadosamente o frasco para injetáveis e dissolva completamente o conteúdo dentro de 30 minutos, mexendo suave e ocasionalmente, evitando a formação de espuma.

☛DETERIORAÇÃO DO PRODUTO
- O produto pode apresentar uma aparência um pouco turva após a reconstituição. Isto não tem efeito sobre o desempenho do produto. A presença de partículas indica deterioração.
- Não use o produto se houver evidência visível de contaminação ou dano (por exemplo, partículas após a reconstituição).
- Não utilizar o calibrador caso haja danos na embalagem que possam causar algum efeito sobre o desempenho do produto (ex. vazamentos).

☛ESTABILIDADE
Antes da reconstituição:
- Conservado a 2-8 °C e ao abrigo da luz.
- Não utilizar após as datas de validade indicadas nos rótulos
dos frascos.

Após a reconstituição:
- Esses produtos devem ser tampados imediatamente e firmemente para evitar contaminação e evaporação.

- Estabilidade dos constituintes:
Entre 15 e 25 °C : 8 horas
Entre 2 e 8 °C : 2 dias
Entre -25 e -15 °C : 4 semanas (congelar apenas uma única vez)

Excepções:
- Estabilidade da bilirrubina total (a conservar ao abrigo da luz) :
Entre 15 e 25 °C : 6 horas
Entre 2 e 8 °C : 1 dia
Entre -25 e -15 °C : 2 semanas (congelar apenas uma única vez)
- Estabilidade da bilirrubina direta (a conservar ao abrigo da luz) :
Entre 15 e 25 °C : 3 horas
Entre 2 e 8 °C : 8 horas
Entre -25 e -15 °C : 2 semanas (congelar apenas uma única vez)

***Observação**: Conservar os frascos bem fechados e ao abrigo da luz.*

☛PROCEDIMENTO
Para usar ELICAL 2, siga o procedimento descrito nas instruções de uso do reagente ELITech Clinical Systems utilizado.

☛LIMITAÇÕES
O uso de ELICAL 2 foi validado com o sistema ELITech (analisador e reagentes listados na folha de valores).
O uso de qualquer outro sistema deve ser validado pelo laboratório.

☛VALORES
As concentrações são indicadas na folha de valores colocada no kit.
Para usuários de instrumentos Selectra que permitem a importação de dados para testes, calibradores e controles, se o código de barras correspondente, disponível na folha de valores.

☛DECLARAÇÃO DE INCIDENTE GRAVE
Notifique o fabricante (através do seu distribuidor) e a autoridade competente da União Européia em que o usuário e/ou o paciente está estabelecido, de qualquer incidente grave que tenha ocorrido em relação ao dispositivo.
Para outras jurisdições, a declaração de incidente grave deve estar de acordo com as normas locais, requisitos regulatórios estaduais e federais.
Ao relatar um incidente grave, você fornece informações que podem contribuir para o segurança de dispositivos médicos *in vitro*.

☛ASSISTÊNCIA TÉCNICA
Entre em contato com o seu distribuidor local ou com a ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Ελληνικά - EL

☛ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ
Τα εν λόγω *in vitro* διαγνωστικά προορίζονται για τον ποιοτικό προσδιορισμό της απόδοσης των ποσοτικών τεστ της ELITech Clinical Systems καταγεγραμμένα στο φύλλο τιμών.
Τα εν λόγω *in vitro* διαγνωστικά προορίζονται μόνο για επαγγελματική χρήση.

☛ΣΥΣΤΑΣΗ
- Τα λυοφιλοποιημένα προϊόντα που ετοιμάζονται για ανθρώπινο ορό είναι δεσμευμένα με χημικά και βιολογικά πρόσθετα.
- Αζίδια του νατρίου < 0.1 % (w/w)
- Οι ελεγχόμενες συγκεντρώσεις για κάθε αναλυτή είναι συγκεκριμένες σύμφωνα με την παρτίδα.

☛ΑΠΑΙΤΟΥΜΕΝΑ ΥΛΙΚΑ ΠΟΥ ΔΕΝ ΣΥΜΠΕΡΙΛΑΜΒΑΝΟΝΤΑΙ
- Αντιδραστήρια της ELITech Clinical Systems καταγεγραμμένα στο φύλλο τιμών.
- Γενικός Εργαστηριακός Εξοπλισμός.

☛ΙΧΝΗΛΑΣΙΜΟΤΗΤΑ
Η ιχνηλασιμότητα ορίζεται στο φύλλο τιμών που συμπεριλαμβάνεται στο κιτ.

☛ΠΡΟΦΥΛΑΞΕΙΣ ΧΡΗΣΗΣ ΚΑΙ ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ
- Κάθε μονάδα ανρθρώπινου αίματος που χρησιμοποιείται για την Παρασκευή αυτών των προϊόντων έχει ελεγχθεί και βρεθεί αρνητική/ μη-αντιδρούσα στην παρουσία HbsAg, HCV και HIV1/2. Οι μέθοδοι που χρησιμοποιούνται είναι εγκεκριμένες από τον FDA ή σύμφωνες με την Ευρωπαϊκή Οδηγία 98/79/EC, Παράρτημα II, Λίστα Α. Μολονότι και εφόσον ο κίνδυνος μόλυνσης δεν μπορεί να αποκλειστεί εντελώς, τα εν λόγω προϊόντα πρέπει να χειρίζονται ως πιθανώς μολυσματικά. Σε περίπτωση έκθεσης, ακολουθείστε τις οδηγίες των αρμόδιων υγειονομικών αρχών.
- Πάρτε προφυλάξεις όταν χειρίζεστε σπασμένα γυάλινα φιαλίδια καθώς οι αιχμηρές γωνίες μπορεί να τραυματίσουν τον χρήστη.
- Τα συγκεκριμένα προϊόντα περιέχουν αζίδια του νατρίου που μπορεί να αντιδράσει με το χαλκό ή το μόλυβδο των σωληνώσεων δημιουργώντας πιθανά εκρηκτικά αζωτούχα μέταλλα. Όταν απορρίπτονται στην αποχέτευση τα αντιδραστήρια αυτά, να ξεπλένετε πάντοτε με άφθονο νερό για την αποφυγή συσσώρευσης αζιδίων.
- Λάβετε συνήθεις προφυλάξεις και εφαρμόστε καλή εργαστηριακή πρακτική.
- Χρησιμοποιήστε μόνο καθαρά ή μίας χρήσης εργαστηριακά σκεύη για την αποφυγή επιμολύνσεων.
- Συμβουλευτείτε το Δελτίο Δεδομένων Ασφαλείας (SDS) για σωστό χειρισμό.

☛ΔΙΑΧΕΙΡΙΣΗ ΑΠΟΒΛΗΤΩΝ
Απόρριψη όλων των αποβλήτων πρέπει να γίνεται σύμφωνα με τις τοπικές, εθνικές και ομοσπονδιακές ρυθμιστικές απαιτήσεις (παρακαλώ ανατρέξτε στο Δελτίο Δεδομένων Ασφαλείας (SDS)).

☛ΠΡΟΕΤΟΙΜΑΣΙΑ
- Χτυπήστε απαλά την φιάλη ώστε το υλικό ελέγχου να βρίσκεται στο κάτω μέρος της φιάλης.
- Ανοίξτε προσεκτικά το φιαλίδιο, αποφεύγοντας την απώλεια της λυοφιλιωμένης ουσίας.
- Προσθέστε **ακριβώς 3 mL απεσταγμένου/ απιονισμένου νερού**.
- Κλείστε το φιαλίδιο προσεκτικά και διαλύστε εντελώς το περιεχόμενο εντός 30 λεπτών με ελαφρύ ανακάτεμα αποφεύγοντας την δημιουργία αφρού.

☛ΑΛΛΟΙΩΣΗ ΤΟΥ ΠΡΟΪΟΝΤΟΣ
- Μετά την ανασύσταση : Ο βαθμονομητής μπορεί να παρουσιάζει μία ελαφρά θολή εμφάνιση. Αυτή δεν έχει καμία επίδραση στην απόδοση του προϊόντος. Η παρουσία μεριδίων μπορεί να υποδεικνύει καταστροφή.
- Μην χρησιμοποιείτε το προϊόν αν υπάρχει εμφανής ένδειξη μόλυνσης ή αλλοίωσης (πχ σωματίδια μετά την ανασύσταση).
- Αλλοίωση στο φιαλίδιο μπορεί να έχει επίδραση στην απόδοση του προϊόντος. Να μην χρησιμοποιείται το προϊόν αν υπάρχει εμφανής απόδειξη αλλοίωσης (πχ διαρροή)

☛ΣΤΑΘΕΡΟΤΗΤΑ
Πριν την ανασύσταση:
- Αποθήκευση στους 2-8ο C μακριά από το φως.
- Να μην χρησιμοποιείται πέραν των ημερομηνιών λήξης που
αναγράφονται στις ετικέτες των φιαλιδίων.

Μετά την ανασύσταση:
- Μη χρησιμοποιείτε μετά τις ημερομηνίες λήξης που αναφέρονται στις ετικέτες των φιαλιδίων.

- Σταθερότητα των συστατικών:
Στους 15 έως 25ο C : 8 ώρες
Στους 2 έως 8ο C : 2 ημέρες
Στους -25 έως -15ο C : 4 εβδομάδες (μία φορά κατάψυξη)

Εξαιρέσεις:
- Σταθερότητα ολικής χολερυθρίνης (όταν αποθηκεύεται μακριά από φως)
Στους 15 έως 25ο C : 6 ώρες
Στους 2 έως 8ο C : 1 ημέρα
Στους -25 έως -15ο C : 2 εβδομάδες (μία φορά κατάψυξη)
-Σταθερότητα άμεσης χολερυθρίνης (όταν αποθηκεύεται μακριά από φως)
Στους 15 έως 25ο C : 3 ώρες
Στους 2 έως 8ο C : 8 ώρες
Στους -25 έως -15ο C : 2 εβδομάδες (μία φορά κατάψυξη)
***Σημείωση**: Αποθηκεύστε τα φιαλίδια ερμητικά πωματισμένα και προστατευμένα από το φως όταν δε χρησιμοποιούνται.*

☛ΔΙΑΔΙΚΑΣΙΑ
Για την χρήση ELICAL 2, ακολουθείστε την περιγραφόμενη διαδικασία στις οδηγίες χρήσης του αντιδραστηρίου της ELITech Clinical Systems που χρησιμοποιείται.

☛ΠΕΡΙΟΡΙΣΜΟΙ
Την χρήση ELICAL 2 έχει επικυρωθεί με τα συστήματα της ELITech (Αναλυτές και αντιδραστήρια είναι καταγεγραμμένα στο φύλλο τιμών).
Η χρήση οποιουδήποτε άλλου συστήματος πρέπει να επικυρωθεί από το εργαστήριο.

☛ΤΙΜΕΣ
Οι συγκεντρώσεις υποδεικνύονται στο φύλλο τιμών μου συμπεριλαμβάνεται στο κιτ.
Για να επιτρέπεται η εισαγωγή δεδομένων τέστ, βαθμονομητών και ορών ελέγχου στους χρήστες μηχανημάτων Selectra, χρησιμοποιείστε τον ανάλογο γραμμικό κώδικα διαθέσιμο στο φύλλο τιμών.

☛ΔΗΛΩΣΗ ΣΟΒΑΡΟΥ ΑΤΥΧΗΜΑΤΟΣ
Παρακαλώ ενημερώστε τον κατασκευαστή (μέσω του διανομέα σας) και τις αρμόδιες αρχές του Κράτους Μέλους της ευρωπαϊκής ένωσης στον οποίο ο χρήστης ή/και ο ασθενής είναι εγκατεστημένος, για κάθε σοβαρό ατύχημα που μπορεί να συμβεί σε σχέση με το μηχάνημα. Για λοιπές δικαιοδοσίες, η δήλωση σοβαρού ατυχήματος πρέπει να συμφωνεί με τις τοπικές, εθνικές και ομοσπονδιακές ρυθμιστικές απαιτήσεις. Αναφέροντας ένα σοβαρό ατύχημα, παρέχετε πληροφορίες που μπορεί να συμβάλλουν στην ασφάλεια των *in vitro* ιατρικών μηχανημάτων.

☛ΤΕΧΝΙΚΗ ΒΟΗΘΕΙΑ
Επικοινωνήστε με τον τοπικό σας διανομέα ή την ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

☛SYMBOLES/ SYMBOLS/ SÍMBOLOS/ ΣΥΜΒΟΛΑ
- Les symboles utilisés sont décrits dans la norme ISO-15223-1 hormis ceux présentés ci-dessous.
- Symbols used are defined on ISO-15223-1 standard, except those presented below.
- Los símbolos utilizados son descritos en la norma ISO-15223-1 a la excepción de los presentados a continuación.
- Os símbolos utilizados são definidos na norma ISO-15223-1, exceto os apresentados abaixo.
- Τα χρησιμοποιούμενα σύμβολα ορίζονται στο πρότυπο ISO 15223-1, εκτός από αυτά που παρουσιάζονται παρακάτω

CONT	Contenu / Content / Contiene/ Conteúdo / περιεχόμενο
CAL	Calibrant / Calibrator / Calibrador / Calibrador / Βαθμονομητής
RCNS : X mL	Reconstituer avec x mL / Reconstitute with x mL / Reconstituir con x mL / Reconstituir com x mL / Ανασύσταση με x mL
☛	Modification par rapport à la version précédente/Modification from previous version/ Modificación con respecto a la versión anterior/ Modificação relativamente à versão anterior/ Τροποποίηση από προηγούμενη έκδοση
CE	Conformité Européenne / European Conformity / Conformidad Europea / Conformidade Europeia / Ευρωπαϊκή Συμμόρφωση

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

ELITROL I
ELITROL II

CONT
ELITROL I ; CONT-0060 : 10 x 5 mL
ELITROL II ; CONT-0160 : 10 x 5 mL

FTCE-CONT-5-v6 (07/2020)

Français - FR

☛USAGE PRÉVU
Ces dispositifs de diagnostic *in vitro* sont destinés au contrôle qualité des performances des tests quantitatifs ELITech listés dans la fiche de valeurs.
Ces dispositifs de diagnostic *in vitro* sont uniquement destinés aux professionnels.

☛COMPOSITION
- Produit sous forme lyophilisée préparé à partir de sérum humain contenant des additifs chimiques et biologiques.
- Les concentrations pour chaque analyte à doser sont spécifiques à chaque lot.

☛MATÉRIELS REQUIS MAIS NON FOURNIS
- Réactifs ELITech Clinical Systems listés dans la fiche de valeurs.
- Equipement général de laboratoire.

☛TRACABILITE
La traçabilité est indiquée dans la fiche technique du réactif ELITech Clinical Systems utilisé en combinaison avec le calibrant recommandé.

☛PRÉCAUTIONS D'EMPLOI ET MISES EN GARDE
- Chaque unité de sang humain utilisée pour la fabrication de ces produits a été testée et trouvée négative/non-réactive pour la présence d'HBsAg, HCV et HIV1/2. Les méthodes utilisées étaient approuvées par la FDA. Cependant le risque d'infection ne pouvant être exclu avec certitude par aucune méthode, ces produits doivent être manipulés comme étant potentiellement infectieux. En cas d'exposition, suivre les directives des autorités sanitaires compétentes.
- Prendre les précautions lors de la manipulation de flacons de verre brisés, car les bords tranchants peuvent blesser l'utilisateur.
- Respecter les précautions d'usage et les bonnes pratiques de laboratoire.
- Utiliser du matériel de laboratoire propre ou à usage unique afin d'éviter toute contamination.
- Consulter la fiche de données de sécurité (FDS) pour une manipulation appropriée.

☛TRAITEMENT DES DÉCHETS
L'élimination de tous les déchets doit être effectuée conformément aux exigences réglementaires locales, d'état et fédérales (veuillez-vous référer à la fiche de données de sécurité (FDS)).

☛PRÉPARATION
- Tapoter doucement le flacon pour que le matériel de contrôle soit en bas du flacon.
- Ouvrir avec précaution le flacon en évitant la perte de poudre lyophilisée.
- Ajouter **précisément 5 mL d'eau distillée ou désionisée**.
- Reboucher le flacon avec soin et dissoudre le contenu complètement dans les 30 minutes en remuant délicatement le flacon et en évitant la formation de mousse.

Remarque importante : Pour réactiver la phosphatase alcaline, laissez reposer le flacon reconstitué à 15 - 25 °C pendant une heure.

☛DÉTÉRIORATION DU PRODUIT
- Le produit peut présenter un aspect légèrement trouble après reconstitution. Cela n'a aucun effet sur les performances du produit. Toute présence de particules serait le signe d'une détérioration.
- Ne pas utiliser le produit s'il y a des signes évidents de détérioration biologique ou chimique (ex : particules après reconstitution).
- Un flacon endommagé peut avoir un impact sur les performances du produit. Ne pas utiliser le produit si les flacons présentent des signes physiques de détérioration (par exemple, fuite).

☛STABILITÉ
Avant reconstitution :
- Stocker à 2-8 °C et à l'abri de la lumière.
- Ne pas utiliser après la date d'expiration indiquée sur l'étiquette du flacon.
Après reconstitution :
- Ces produits doivent être immédiatement et correctement refermés afin d'éviter toute contamination ou évaporation.
- Stabilité des constituants :
Entre 2 et 8 °C : 5 jours
Entre -25 et -15 °C : 4 semaines (ne congeler qu'une seule fois)

Exceptions :
- Stabilité de la bilirubine totale (à conserver à l'abri de la lumière) :
Entre 2 et 8 °C : 24 heures
Entre -25 et -15 °C : 5 jours (ne congeler qu'une seule fois)

- Stabilité de la bilirubine directe (à conserver à l'abri de la lumière) :
Entre 2 et 8 °C : 8 heures
Entre -25 et -15 °C : 5 jours (ne congeler qu'une seule fois)

- Stabilité de la phosphatase alcaline :
Entre 2 et 8 °C : 24 heures
Entre -25 et -15 °C : 4 semaines (ne congeler qu'une seule fois)

Note :
- Conserver les flacons bien fermés et à l'abri de la lumière après reconstitution.
- Bien mélanger avant utilisation.
- La décongélation des échantillons à 37°C ainsi que leur agitation énergique (vortex) doivent être évitées car elles peuvent dénaturer la ferritine.

☛PROCÉDURE
Pour utiliser ELITROL I & II, suivre la procédure décrite dans la fiche technique du réactif ELITech Clinical Systems utilisé.

☛LIMITATIONS
L'utilisation de ELITROL I & II a été validée avec les systèmes ELITech (Automates et réactifs listés dans la fiche de valeurs).
L'utilisation sur un autre système doit être validée par le laboratoire.

☛VALEURS
Les concentrations sont indiquées dans la fiche de valeurs incluse dans le coffret.
Les valeurs obtenues par les laboratoires peuvent être différentes de celles annoncées. La technique, l'équipement et des erreurs expérimentales peuvent induire ces différences. Par conséquent, il est recommandé à chaque laboratoire de redéfinir ses propres normes.
Pour les utilisateurs d'automates Selectra permettant l'import de tests, de calibrants et de contrôles, utiliser le code barre correspondant, disponible sur la fiche de valeurs.

☛DECLARATION DES INCIDENTS GRAVES
Veuillez notifier au fabricant (par l'intermédiaire de votre distributeur) et à l'autorité compétente de l'Etat membre de l'union européenne dans lequel l'utilisateur et/ou le patient est établi, les cas d'incident grave survenu en lien avec le dispositif.
Pour les autres juridictions, la déclaration d'incident grave doit être effectuée conformément aux exigences réglementaires locales, d'état et fédérales.
En signalant les incidents graves, vous contribuez à fournir davantage d'informations sur la sécurité des dispositifs médicaux de diagnostic *in vitro*.

☛TECHNICAL ASSISTANCE
Contacter votre distributeur local ou ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

English - EN

☛INTENDED USE
These *in vitro* diagnostic devices are intended for the quality control of the performances of ELITech Clinical Systems quantitative tests listed in the value sheet.
These *in vitro* diagnostic devices are for professional use only.

☛COMPOSITION
- Lyophilized product prepared from human serum spiked with chemical and biological additives.
- Concentrations for each analyte to test are lot-specific.

☛MATERIALS REQUIRED BUT NOT PROVIDED
- ELITech Clinical Systems reagents listed in the value sheet.
- General Laboratory equipment.

☛TRACEABILITY
The traceability is indicated on the instructions for use of the ELITech Clinical Systems reagent used in combination with the recommended calibrator.

☛PRECAUTIONS FOR USE AND WARNINGS
- Each unit of human blood used in the manufacture of these products was tested and found to be negative/non-reactive for the presence of HbsAg, HCV and HIV1/2. The methods used were FDA approved. Nevertheless, since the risk of infection cannot be fully excluded these products must be handled as potentially infectious. In case of exposure, follow the guidelines of the competent health authorities.
- Take precautions when handling broken glass vials as sharp edges can injure the user.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- Consult Safety Data Sheet (SDS) for a proper handling.

☛WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

☛PREPARATION
- Gently tap the vial so that the control material can be at the bottom of the vial.
- Carefully open the vial, avoiding the loss of lyophilizate.
- Add **exactly 5 mL of distilled or deionized water.**
- Carefully close the vial and dissolve the contents completely within 30 minutes by occasional gentle stirring avoiding the formation of foam.

Important: To reactivate the alkaline phosphatase, allow the reconstituted control serum to stand for one hour at 15–25 °C.

☛PRODUCT DETERIORATION
- The product may present a slightly hazy appearance after reconstitution. This has no effect on the performances of the product. All presence of particules would indicate deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter after reconstitution).
- Damage to the container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages).

☛STABILITY
Prior to reconstitution :
- Store at 2-8 °C and protect from light. Do not freeze.
- Do not use after the expiry date stated on the vial label.
After reconstitution :
- These products should be immediately and tightly capped to prevent contamination and evaporation.
- Stability of the components:
Between 2 and 8 °C : 5 days
Between -25 and -15 °C : 4 weeks (when frozen once)

Exceptions:

- Stability of total bilirubin (when stored protected from light) :
Between 2 and 8 °C : 24 hours
Between -25 and -15 °C : 5 days (when frozen once)

- Stability of direct bilirubin (when stored protected from light) :
Between 2 and 8 °C : 8 hours
Between -25 and -15 °C : 5 days (when frozen once)

- Stability of alkaline phosphatase:
Between 2 and 8 °C : 24hours
Between -25 and -15 °C : 4 weeks (when frozen once)

Note:
- Store the vials tightly capped and protected from light after reconstitution.
- Mix content thoroughly prior to use.
- Thawing frozen specimen at 37°C, and vigorous mixing (vortex), should be avoided as this may denature ferritin.

☛PROCEDURE
To use ELITROL I & II, follow the procedure described in the instructions for use of the ELITech Clinical Systems reagent used.

☛LIMITATIONS
Using ELITROL I & II has been validated with the ELITech systems (Analyzers and reagents listed in the value sheet).
Using any other system should be validated by the laboratory.

☛VALUES
The concentrations are indicated in the value sheet enclosed in the kit.
Individual laboratories may obtain values different from those announced. Technique, equipment and experimental error may produce slightly different values. Each laboratory should determine their own mean values.
For users of Selectra instruments allowing data import for tests, calibrators and controls, use corresponding barcode, available on the value sheet.

☛DECLARATION OF SERIOUS INCIDENT
Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements. By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

☛ASSISTANCE TECHNIQUE
Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Español - ES

☛USO PREVISTO
Estos dispositivos de diagnóstico *in vitro* están diseñados para el control de calidad del rendimiento de las pruebas cuantitativas ELITech Clinical Systems listadas en la hoja de valores.
Estos dispositivos de diagnóstico *in vitro* están destinados unicamente para los profesionales.

☛COMPOSICIÓN
- Producto liofilizado preparado a partir de suero humano enriquecido con aditivos químicos y biológicos.
- Las concentraciones de cada analito a analizar son específicas a cada lote.

☛MATERIALES REQUERIDOS PERO NO INCLUIDOS
- Reactivos ELITech Clinical Systems listados en la hoja de valores.
- Equipo de laboratorio de uso general.

☛TRAZABILIDAD
La trazabilidad se indica en el inserto del reactivo ELITech Clinical Systems utilizado en combinación con el calibrador recomendado.

☛PRECAUCIONES DE USO Y ADVERTENCIAS
- Cada unidad de sangre humana utilizada en la fabricación de estos productos fue analizada y resultó ser negativa / no reactiva ante la presencia de HbsAg, VHC y VIH1/2. Los métodos utilizados fueron aprobados de conformidad por la FDA. Sin embargo, dado que el riesgo de infección no puede excluirse por completo, estos productos deben manejarse como potencialmente infecciosos. En caso de exposición, siga las indicaciones de las autoridades sanitarias competentes.
- Tenga precauciones al manipular viales de vidrio roto, ya que los bordes afilados pueden dañar al usuario.
- Respetar las precauciones de uso y las buenas prácticas de laboratorio.
- Para evitar contaminaciones utilizar equipo nuevo o completamente limpio.
- Consulte la Hoja de Datos de Seguridad (SDS) para un manejo adecuado.

☛TRATAMIENTO DE LOS RESIDUOS
Todos los materiales de desecho deben eliminarse de acuerdo con los requisitos regulatorios locales, estatales y federales (diríjase a la hoja de seguridad (SDS)).

☛PREPARACIÓN
- Golpee suavemente el frasco para que el material de control quede en el fondo del frasco.
- Destapar cuidadosamente el frasco con el fin de evitar la pérdida de material liofilizado.
- Agregar exactamente 5 mL de agua destilada o de agua desionizada.
- Cierre cuidadosamente el vial y disuelva el contenido por completo durante 30 minutos mezclando suavemente para evitar la formación de espuma.

Importante: Para reactivar la fosfatasa alcalina, deje el vial reconstituido descansar a 15 - 25 ° C durante una hora.

☛DETERIORACIÓN DEL PRODUCTO
- El producto puede presentar un aspecto ligeramente turbio después de reconstitución, esto no afecta el rendimiento del producto. La presencia de partículas es un signo de deterioro.
- No utilice el producto si este presenta signos evidentes de contaminación o deterioro (p. ej, partículas después de reconstitución).
- Un frasco dañado puede tener un impacto en el rendimiento del producto. No utilice el producto si este tiene signos físicos de deterioro (p. ej, fugas).

☛ESTABILIDAD
Antes de reconstituir :
- Conservar a 2-8 °C y protegidos de la luz. No congelar.
- No utilice después de la fecha de caducidad indicada en la etiqueta de los frascos.
Después de reconstituir :
- Estos productos deben ser bien cerrados de inmediato para evitar contaminación y evaporación.
- Estabilidad de los componentes:
Entre 2 y 8 °C : 5 días
Entre -25 y - 15 °C : 4 semanas (no congelar más de una vez)

Excepciones:

- Estabilidad de la bilirrubina total (proteger de la luz) :
Entre 2 y 8 °C : 24 horas
Entre -25 y -15 °C : 5 días (no congelar más de una vez)

- Estabilidad de la bilirrubina directa (proteger de la luz) :
Entre 2 y 8 °C : 8 horas
Entre -25 y -15 °C : 5 días (no congelar más de una vez)

- Estabilidad de la fosfatasa alcalina:
Entre 2 y 8 °C : 24 horas
Entre -25 y -15 °C : 4 semanas (no congelar más de una vez)

Nota:
- Mantenga los frascos bien cerrados y protéjalos de la luz después de reconstituir.
- Mezclar bien antes de utilizar.
- La descongelación de las muestras a 37 ° C así como una agitación vigorosa (vórtice) deben evitarse ya que pueden desnaturalizar la ferritina.

☛PROCEDIMIENTO
Para utilizar ELITROL I & II, siga el procedimiento descrito en el inserto del reactivo ELITech Clinical Systems utilizado.

☛LIMITACIONES
El uso de ELITROL I & II ha sido validado con los sistemas ELITech (equipos y reactivos enumerados en la hoja de valores).
El uso de cualquier otro sistema debe ser validado por el laboratorio.

☛VALORES
Las concentraciones son indicadas en la ficha de valores incluida en el kit.
Los laboratorios pueden obtener valores differentes de los valores anunciados. Procedimiento, equipo, errores experimentales pueden producir valores con pequeñas diferencias. Se recomienda que cada laboratorio determine su propia media para estos controles.
Para usuarios de los equipos Selectra que permiten la importación de pruebas, calibradores y controles, use el código de barras correspondiente, disponible en la hoja de valores.

☛DECLARACIÓN DE INCIDENTES GRAVES
Por favor notifique al fabricante (por medio de su distribuidor) y autoridad competente del Estado miembro de la Unión Europea en donde el usuario o paciente radique, de cualquier incidente grave que se produzca con relación al dispositivo.
Para otras jurisdicciones, la declaración de incidentes graves debe realizarse de acuerdo con los requisitos reglamentarios locales, estatales y federales. Reportando incidentes graves usted contribuye a proporcionar más información sobre la seguridad del dispositivo médico de diagnóstico *in vitro*.

☛ASISTENCIA TÉCNICA
Contacte a su distribuidor local o con ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Português - PT

☛UTILIZAÇÃO PREVISTA
Estes dispositivos de diagnóstico *in vitro* são destinados ao controle de qualidade dos desempenhos dos testes quantitativos ELITech Clinical Systems listados na folha de valores.
Estes dispositivos de diagnóstico *in vitro* são apenas para uso profissional.

☛COMPOSIÇÃO
- Produto liofilizado preparado a partir de soro humano enriquecido com aditivos químicos e biológicos.
- As concentrações de cada analito a ser testado são específicas de cada lote.

☛MATERIAIS NECESSÁRIOS MAS NÃO FORNECIDOS
- ELITech Clinical Systems reagentes listados na folha de valores.
- Equipamento geral de laboratório.

☛RASTREABILIDADE
A rastreabilidade é indicada nas instruções de uso do reagente ELITech Clinical Systems utilizado em combinação com o calibrador recomendado.

☛PRECAUÇÕES DE USO E AVISOS
Cada unidade de sangue humano utilizada na fabricação desses produtos foi testada e se mostrou negativa / não reativa para a presença de HbsAg, HCV e HIV1 / 2. Os métodos utilizados foram aprovados e liberados pela FDA. No entanto, como o risco de infecção não pode ser totalmente excluído, esses produtos devem ser manuseados como potencialmente infecciosos. Em caso de exposição, siga as orientações das autoridades sanitárias competentes.
- Tome precauções ao manusear frascos de vidro quebrados, pois bordas afiadas podem ferir o usuário.
- Respeitar as precauções de utilização e as boas práticas de laboratório.
- Utilizar material de laboratório limpo ou destinado a uma única utilização de modo a evitar qualquer contaminação.
- Consulte a ficha de dados de segurança (SDS) para obter um manuseio adequado.

☛TRATAMENTO DOS RESÍDUOS
O descarte de todo material residual deve estar de acordo com os requisitos regulamentares locais, estaduais e federais (consulte a Ficha de dados de segurança (SDS)).

☛PREPARAÇÃO
- Bata levemente no frasco para que o material de controle possa estar no fundo do frasco.
- Abrir cuidadosamente o frasco, evitando a perda de pó liofilizado.
- Acrescentar **exatamente 5 mL de água destilada ou deionizada**.
- Feche cuidadosamente o frasco para injetáveis e dissolva completamente o conteúdo dentro de 30 minutos, mexendo suave e ocasionalmente, evitando a formação de espuma.

Observação importante: Para reativar a fosfatase alcalina, deixe o frasco reconstituído descansar a 15 - 25 °C por uma hora.

☛DETERIORAÇÃO DO PRODUTO
- O produto pode apresentar uma aparência um pouco turva após a reconstituição. Isto não tem efeito sobre o desempenho do produto. A presença de partículas indica deterioração.
- Não use o produto se houver evidência visível de contaminação ou dano (por exemplo, partículas após a reconstituição).
- Não utilizar o calibrador caso haja danos na embalagem que possam causar algum efeito sobre o desempenho do produto (ex. vazamentos).

☛ESTABILIDADE
Antes da reconstituição :
- Conservar a 2-8 °C e ao abrigo da luz.
- Não utilizar após as datas de validade indicadas nos rótulos dos frascos.
Após a reconstituição :
- Esses produtos devem ser tampados imediatamente e firmemente para evitar contaminação e evaporação.
- Estabilidade dos constituintes:
Entre 2 e 8 °C : 5 dias
Entre -25 e -15 °C : 4 semanas (congelar apenas uma única vez)

Excepções:

- Estabilidade da bilirrubina total (a conservar ao abrigo da luz) :
Entre 2 e 8 °C : 24 horas
Entre -25 e -15 °C : 5 dias (congelar apenas uma única vez)

- Estabilidade da bilirrubina direta (a conservar ao abrigo da luz) :
Entre 2 e 8 °C : 8 horas
Entre -25 e -15 °C : 5 dias (congelar apenas uma única vez)

- Estabilidade do fosfatase alcalina :
Entre 2 e 8 °C : 24 horas
Entre -25 e -15 °C : 4 semanas (congelar apenas uma única vez)

Observação:
- Armazene os frascos bem fechados e protegidos da luz após a reconstituição.
- Misture bem o conteúdo antes de usar.
- Descongelar a amostra a 37 ° C e a mistura vigorosa (vórtice) devem ser evitados, pois isso pode desnaturar a ferritina.

☛PROCEDIMENTO
Para usar ELITROL I & II, siga o procedimento descrito nas instruções de uso do reagente ELITech Clinical Systems utilizado.

☛LIMITAÇÕES
O uso de ELITROL I & II foi validado com o sistema ELITech (analisador e reagentes listados na folha de valores).
O uso de qualquer outro sistema deve ser validado pelo laboratório.

☛VALORES
As concentrações são indicadas na folha de valores colocada no kit.
Os valores obtidos pelos laboratórios podem ser diferentes dos anunciados. A técnica, o equipamento e erros experimentais podem induzir essas diferenças. Consequentemente aconselha-se que cada laboratório redefina as suas próprias normas.
Para usuários de instrumentos Selectra que permitem a importação de dados para testes, calibradores e controles, se o código de barras correspondente, disponível na folha de valores.

☛DECLARAÇÃO DE INCIDENTE GRAVE
Notifique o fabricante (através do seu distribuidor) e a autoridade competente da União Européia em que o usuário e/ou o paciente está estabelecido, de qualquer incidente grave que tenha ocorrido em relação ao dispositivo.
Para outras jurisdições, a declaração de incidente grave deve estar de acordo com as normas locais, requisitos regulatórios estaduais e federais. Ao relatar um incidente grave, você fornece informações que podem contribuir para o segurança de dispositivos médicos *in vitro*.

☛ASSISTÊNCIA TÉCNICA
Entre em contato com o seu distribuidor local ou com a ELITech Clinical Systems SAS. (CCsupport@elitechgroup.com).

Ελληνικά - EL

☛ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ
Τα εν λόγω *in vitro* διαγνωστικά προορίζονται για τον ποιοτικό προσδιορισμό της απόδοσης των ποσοτικών τεστ της ELITech Clinical Systems καταγεγραμμένα στο φύλλο τιμών.
Τα εν λόγω *in vitro* διαγνωστικά προορίζονται μόνο για επαγγελματική χρήση.

☛ΣΥΣΤΑΣΗ
- Τα λυοφιλοποιημένα προϊόντα που ετοιμάζονται για ανθρώπινο ορό είναι δεσμευμένα με χημικά και βιολογικά πρόσθετα.
- Οι ελεγχόμενες συγκεντρώσεις για κάθε αναλυτή είναι συγκεκριμένες σύμφωνα με την παρτίδα.

☛ΑΠΑΙΤΟΥΜΕΝΑ ΥΛΙΚΑ ΠΟΥ ΔΕΝ ΣΥΜΠΕΡΙΛΑΜΒΑΝΟΝΤΑΙ
- Αντιδραστήρια της ELITech Clinical Systems καταγεγραμμένα στο φύλλο τιμών.
- Γενικός Εργαστηριακός Εξοπλισμός.

☛ΙΧΝΗΛΑΣΙΜΟΤΗΤΑ
Η ιχνηλασιμότητα ορίζεται στις οδηγίες χρήσης του αντιδραστηρίου της ELITech Clinical Systems που χρησιμοποιείται σε συνδυασμό με τον προτεινόμενο βαθμονομητή.

☛ΠΡΟΦΥΛΑΞΕΙΣ ΧΡΗΣΗΣ ΚΑΙ ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ
- Κάθε μονάδα ανρθρώπινου αίματος που χρησιμοποιείται για την Παρασκευή αυτών των προϊόντων έχει ελεγχθεί και βρεθεί αρνητική/ μη-αντιδρούσα στην παρουσία HbsAg, HCV και HIV1/2. Οι μέθοδοι που χρησιμοποιούνται είναι εγκεκριμένες από τον FDA. Μολονότι και εφόσον ο κίνδυνος μόλυνσης δεν μπορεί να αποκλειστεί εντελώς, τα εν λόγω προϊόντα πρέπει να χειρίζονται ως πιθανώς μολυσματικά. Σε περίπτωση έκθεσης, ακολουθείστε τις οδηγίες των αρμόδιων υγειονομικών αρχών.
- Πάρτε προφυλάξεις όταν χειρίζεστε σπασμένα γυάλινα φιαλίδια καθώς οι αιχμηρές γωνίες μπορεί να τραυματίσουν τον χρήστη.
- Λάβετε συνήθεις προφυλάξεις και εφαρμόστε καλή εργαστηριακή πρακτική.
- Χρησιμοποιήστε μόνο καθαρά ή μίας χρήσης εργαστηριακά σκεύη για την αποφυγή επιμολύνσεων.
- Συμβουλευτείτε το Δελτίο Δεδομένων Ασφαλείας (SDS) για σωστό χειρισμό.

☛ΔΙΑΧΕΙΡΙΣΗ ΑΠΟΒΛΗΤΩΝ
Απόρριψη όλων των αποβλήτων πρέπει να γίνεται σύμφωνα με τις τοπικές, εθνικές και ομοσπονδιακές ρυθμιστικές απαιτήσεις (παρακαλώ ανατρέξτε στο Δελτίο Δεδομένων Ασφαλείας (SDS)).

☛ΠΡΟΕΤΟΙΜΑΣΙΑ
- Χτυπήστε απαλά την φιάλη ώστε το υλικό ελέγχου να βρίσκεται στο κάτω μέρος της φιάλης.
- Ανοίξτε προσεκτικά το φιαλίδιο, αποφεύγοντας την απώλεια της λυοφιλιωμένης ουσίας.
- Προσθέστε **ακριβώς 5 mL απεσταγμένου/ απιονισμένου νερού**.
- Κλείστε το φιαλίδιο προσεκτικά και διαλύστε εντελώς το περιεχόμενο εντός 30 λεπτών με ελαφρύ ανακάτεμα αποφεύγοντας την δημιουργία αφρού.

Σημαντικό: Για ενεργοποίηση της αλκαλικής φωσφατάσης, αφήστε τον ανασυσταμένο ορό ελέγχου να παραμείνει για μία ώρα στους 15-25o C.

☛ΑΛΛΟΙΩΣΗ ΤΟΥ ΠΡΟΪΟΝΤΟΣ
- Μετά την ανασύσταση : Το προϊόν ελέγχου μπορεί να παρουσιάζει μία ελαφρά θολή εμφάνιση. Αυτή δεν έχει καμία επίδραση στην απόδοση του προϊόντος. Η παρουσία μεριδίων μπορεί να υποδεικνύει καταστροφή.
- Μην χρησιμοποιείτε το προϊόν αν υπάρχει εμφανής ένδειξη μόλυνσης ή αλλοίωσης (πχ σωματίδια μετά την ανασύσταση).
- Αλλοίωση στο φιαλίδιο μπορεί να έχει επίδραση στην απόδοση του προϊόντος. Να μην χρησιμοποιείται το προϊόν αν υπάρχει εμφανής απόδειξη αλλοίωσης (πχ διαρροή).

☛ΣΤΑΘΕΡΟΤΗΤΑ
Πριν την ανασύσταση :
- Αποθηκεύστε στους 2-8 °C και προστατέψτε από το φως.
- Μη χρησιμοποιείτε μετά τις ημερομηνίες λήξης που αναφέρονται στις ετικέτες των φιαλιδίων.
Κατόπιν ανασύστασης :
- Στα εν λόγω προϊόντα πρέπει το πώμα να τοποθετείται αμέσως και σφικτά προς αποφυγή μόλυνσης και εξάτμισης.
- Σταθερότητα των συστατικών:
Στους 2 έως 8ο C : 5 ημέρες
Στους -25 έως -15ο C : 4 εβδομάδες (μία φορά κατάψυξη)

Εξαιρέσεις:

- Σταθερότητα ολικής χολερυθρίνης (όταν αποθηκεύεται μακριά από φως)
Στους 2 έως 8ο C : 24 ώρες
Στους -25 έως -15ο C : 5 ημέρες (μία φορά κατάψυξη)
- Σταθερότητα άμεσης χολερυθρίνης (όταν αποθηκεύεται μακριά από φως)
Στους 2 έως 8ο C : 8 ώρες
Στους -25 έως -15ο C : 5 ημέρες (μία φορά κατάψυξη)

- Σταθερότητα της αλκαλικής φωσφατάσης
Στους 2 έως 8ο C : 24 ώρες
Στους -25 έως -15ο C : 4 εβδομάδες (μία φορά κατάψυξη)

Σημείωση:
- Αποθηκεύστε το φιαλίδιο σφικτά κλειστό και μακριά από το φως μετά την ανασύσταση.
- Αναμίξτε το περιεχόμενο διεξοδικά πριν τη χρήση του.
- Η απόψυξη κατεψυγμένου δείγματος στους 37°C και η έντονη ανάμειξή του (με vortex) πρέπει να αποφεύγετε καθώς μπορεί να αλλοιώσει τη φερριτίνη.

☛ΔΙΑΔΙΚΑΣΙΑ
Για την χρήση ELITROL I & II, ακολουθείστε την περιγραφόμενη διαδικασία στις οδηγίες χρήσης του αντιδραστηρίου της ELITech Clinical Systems που χρησιμοποιείται.

☛ΠΕΡΙΟΡΙΣΜΟΙ
Την χρήση ELITROL I & II έχει επικυρωθεί με τα συστήματα της ELITech (Αναλυτές και αντιδραστήρια είναι καταγεγραμμένα στο φύλλο τιμών).
Η χρήση οποιουδήποτε άλλου συστήματος πρέπει να επικυρωθεί από το εργαστήριο.

☛ΤΙΜΕΣ
Οι συγκεντρώσεις υποδεικνύονται στο φύλλο τιμών μου συμπεριλαμβάνεται στο κιτ.
Μεμονωμένα εργαστήρια μπορεί να λάβουν τιμές διαφορετικές από τις ανακοινώσιμες. Η τεχνική, ο εξοπλισμός και το πειραματικό σφάλμα μπορεί να δώσουν ελαφρώς διαφορετικές τιμές. Κάθε εργαστήριο πρέπει να ορίζει τις δικές του μέσες τιμές.
Για να επιτρέπεται η εισαγωγή δεδομένων τέστ, βαθμονομητών και ορών ελέγχου στους χρήστες μηχανημάτων Selectra, χρησιμοποιείστε τον ανάλογο γραμμικό κώδικα διαθέσιμο στο φύλλο τιμών.

☛ΔΗΛΩΣΗ ΣΟΒΑΡΟΥ ΑΤΥΧΗΜΑΤΟΣ
Παρακαλώ ενημερώστε τον κατασκευαστή (μέσω του διανομέα σας) και τις αρμόδιες αρχές του Κράτους Μέλους της ευρωπαϊκής ένωσης στον οποίο ο χρήστης ή/και ο ασθενής είναι εγκατεστημένος, για κάθε σοβαρό ατύχημα που μπορεί να συμβεί σε σχέση με το μηχάνημα. Για λοιπές δικαιοδοσίες, η δήλωση σοβαρού ατυχήματος πρέπει να συμφωνεί με τις τοπικές, εθνικές και ομοσπονδιακές ρυθμιστικές απαιτήσεις. Αναφέροντας ένα σοβαρό ατύχημα, παρέχετε πληροφορίες που μπορεί να συμβάλλουν στην ασφάλεια των *in vitro* ιατρικών μηχανημάτων.

☛ΤΕΧΝΙΚΗ ΒΟΗΘΕΙΑ
Επικοινωνήστε με τον τοπικό σας διανομέα ή την ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

☛SYMBOLES/ SYMBOLS/ SÍMBOLOS/ ΣΥΜΒΟΛΑ
- Les symboles utilisés sont décrits dans la norme ISO-15223-1 hormis ceux présentés ci-dessous.
- Symbols used are defined on ISO-15223-1 standard, except those presented below.
- Los símbolos utilizados son descritos en la norma ISO-15223-1 a la excepción de los presentados a continuación.
- Os símbolos utilizados são definidos na norma ISO-15223-1, exceto os apresentados abaixo.
- Τα χρησιμοποιούμενα σύμβολα ορίζονται στο πρότυπο ISO 15223-1, εκτός από αυτά που παρουσιάζονται παρακάτω

CONT	Contenu / Content / Contiene/ Conteúdo / περιεχόμενο
CONTROL	Contrôle /Control /Control /Controlo /Ορός Ελέγχου
RCNS : X mL	Reconstituer avec x mL / Reconstitute with x mL / Reconstituir con x mL / Reconstituir com x mL / Ανασύσταση με x mL
☛	Modification par rapport à la version précédente/ Modification from previous version/ Modificación con respecto a la versión anterior/ Modificação relativamente à versão anterior/ Τροποποίηση από προηγούμενη έκδοση
CE	Conformité Européenne / European Conformity / Conformidad Europea / Conformidade Europeia / Ευρωπαϊκή Συμμόρφωση

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.

_____
Eddy Velthuis
Technical Director

LORNE LABORATORIES LTD.

GREAT BRITAIN

SYPHILIS SEROLOGY KIT

DIRECTIONS FOR USE

RPR CARBON KIT: For Detection Of Syphilis.

SUMMARY

At one time, syphilis was a major medical disease with a host of different manifestations transmitted primarily through sexual contact. The advent of penicillin in 1943 changed this. The etiologic agent of syphilis is *Treponema pallidum*, a spiral bacterium (spirochete). The spirochete causes some damage to the heart and the liver, releasing some tissue fragments. The patient's immune system produces antibodies, called reagins, against these fragments. There are two different techniques for the detection of syphilis. TPHA tests, which detect antibodies to *Treponemal pallidum*, and non-treponemal serologic tests, which detect Reagin in infected people.

INTENDED PURPOSE

The reagent is a test reagent intended to be used to qualitatively and semi-quantitatively determine the presence or absence of Reagin (antibodies against Syphilis) in the serum or plasma of patients when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

When used by the recommended techniques, the reagent will agglutinate (clump) in the presence of reagin. No agglutination usually indicates the absence of reagin (see **Limitations**).

KIT DESCRIPTION

Lorne RPR Carbon Kit is a non-treponemal serologic test for the detection of syphilis. The RPR Carbon Antigen contains micro particulate carbon, which aids in the microscopic reading of results. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. All the reagents are supplied at optimum dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8ºC for 7 days or for up to 3 months at or below –20ºC. Specimens must be free from bacterial contamination, fibrin, haemolysis and lipaemia.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents in this kit have been processed to reduce the bio-burden, but are not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
5. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.
6. RPR Positive Control: H319 - Causes serious eye irritation. Follow the precautionary statement given in the SDS.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended that the RPR Positive and Negative Controls are tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Shake all the reagents well before use to ensure homogeneity.
3. Do not interchange components between different kits.
4. All the reagents must be allowed to reach 18-25ºC before use.
5. The circles on the agglutination cards should never be touched with fingers, as this may invalidate the test results.
6. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where reagents are in use.
7. The user must the determine suitability of the kit for use in other techniques.

KIT COMPONENTS PROVIDED

1) RPR Carbon Reagent (White cap, 1x3 mL (150 tests) or 2x5 mL (500 tests)): Carbon particles coated with a lipid complex (cardiolipin, lecithin and cholesterol) in phosphate buffer 20 mmol/L, pH 7.0 containing a preservative.
2) RPR Positive Control (Red cap, 1 mL): Artificial serum with reagin titer ≥ 1/4.
3) RPR Negative Control (Blue cap, 1 mL): Animal serum containing a preservative
4) Dispensing bottle (Green cap, 1 x 2 ml).
5) Dispensing Needle (x1).
6) Disposable agglutination slides.
7) Plastic stirrers.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

a) Pipette capable of accurately delivering 50 µl
b) Mechanical rotating table capable of rotating at 80-100 rpm.
c) 9 g/L saline solution.

QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative Controls into separate circles on the slide test.
3. Swirl the RPR Carbon Reagent gently before using. Invert the dropper assembly and press gently to remove air bubbles from the micropipette.
4. Place the micropipette in a vertical position and perpendicular to the slide, and add one drop (20 µL) of this reagent next to the samples to be tested.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample
6. Place the slide on a mechanical rotating table at 80-100 r.p.m. for 8 min. False positive results could appear if the test is read after more than 8 minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Reactive:** Visible agglutination (medium to large clumps) constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
2. **Weak-Reactive:** Weak agglutination (small clumps) around the periphery of the test area constitutes a weak positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
3. **Negative:** No agglutination constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of reagin.

SEMI QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the quantitative technique using dilutions of the serum in 9 g/L saline solution.
2. Make doubling dilutions of specimen as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Read the test and note the last positive dilution series.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 8-minute rotating period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. RPR carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
2. A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.
4. Bilirubin (≤ 20 mg/dL), hemoglobin (≤ 10 g/L) and lipids (≤ 10 g/L), do not interfere. Rheumatoid factors (≥ 300 IU/mL), interfere. Other substances may interfere[5].
5. False positive or negative results may also occur due to:
   a) Not expelling air from end of needle
   b) Not maintaining dispensing bottle and needle in a vertical position when dispensing the antigen.
   c) When transferring the specimen from the collecting tube some of the specimen being drawn up in to the teat
   d) Contamination of test materials
   e) Improper storage of test materials or omission of reagents
   f) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne RPR Syphilis Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.
3. The reagent sensitivity is calibrated against the WHO 1st International Standard for human syphilitic plasma (NIBSC reference number 05/132).
4. **Prozone effect:** No prozone effect was detected up to titers ≥1/128.
5. **Diagnostic sensitivity:** 100%
6. **Diagnostic specificity:** 100 %.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

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AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	044150A
500 Tests Per Kit	044500A

Lorne Laboratories Limited
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EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
LISS Ready For Use	470020 470250 470025

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This product has been manufactured by Lorne Laboratories Ltd at their facilities which are located at:

Address line 1: Unit 1 Cutbush Park Industrial Estate
Address line 2: Danehill
City: Lower Early
County: Berkhire
Postal code: RG6 4UT
Country: United Kingdom
Telephone number: +44-(0)118 921 2264
Fax number: +44-(0)118 986 4518
Website: www.lornelabs.com
DUNS Number: 732670703

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2016
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 10 April 2019.

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
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File No A12241;
ISO 13485:2003; ISO 9001:2008

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

LORNE LABORATORIES LTD.
MAREA BRITANIE

MEDIU DE ÎMBUNĂTĂŢIRE SEROLOGICĂ
INSTRUCŢIUNI DE UTILIZARE

LISS Ready for use: Pentru potenţarea tehnicilor serologice.

REZUMAT

Reducerea puterii ionice a unui sistem de testare măreşte viteza de legare antigen-anticorp a globulelor roşii. În 1974, Low şi Messeter au demonstrat că o soluţie cu putere ionică joasă îmbunătăţeşte viteza de absorbţie a anticorpilor în prima etapă de aglutinare, permiţând scurtarea timpilor de incubare.

SCOPUL PROPUS

Soluţia LISS Ready for use este o soluţie salină cu putere ionică joasă utilizată pentru determinarea grupei sanguine în procedurile de compatibilitate directă şi screening al anticorpilor atunci când se foloseşte conform tehnicilor recomandate şi prezentate în aceste instrucţiuni de utilizare.

PRINCIPIUL

Când este folosită conform tehnicilor recomandate, soluţia va reduce puterea ionică a unui sistem de testare, va mări viteza de legare antigen-anticorp a globulelor roşii şi va permite o reducere substanţială a timpului de incubare şi o creştere a sensibilităţii de testare cu numeroase specificităţi de anticorpi (consultaţi **Limitări**).

REACTIV

LISS Ready for use Lorne este o soluţie cu putere ionică joasă care conţine glicocol, clorură de sodiu şi tampon fosfat. Reactivul nu conţine sau nu este compus din substanţe CMR, substanţe perturbatoare pentru sistemul endocrin sau care ar putea provoca sensibilizare sau o reacţie alergică în cazul utilizatorului. Reactivul este furnizat la diluarea optimă pentru utilizare cu toate tehnicile recomandate prezentate mai jos, fără să mai fie necesară diluarea sau adăugarea suplimentară. Pentru numărul de referinţă al lotului şi data de expirare, consultaţi **Eticheta flaconului**.

DEPOZITARE

Flacoanele cu reactiv trebuie depozitate la temperaturi cuprinse între 10 şi 30 ºC după primire. Depozitarea prelungită la temperaturi în afara acestui interval poate duce la pierderea accelerată a reactivităţii. Acest reactiv a fost supus unor studii de stabilitate la transport la 37 °C şi –25 °C, conform precizărilor din documentul BS EN ISO 23640:2015.

RECOLTAREA ŞI PREGĂTIREA PROBEI

Probele de sânge pot fi recoltate în EDTA, citrat, anticoagulanţi CPDA sau ca probă coagulată. Probele trebuie testate cât mai curând posibil după recoltare. Dacă survine o întârziere în ce priveşte testarea, păstraţi probele la 2-8 °C. Probele care prezintă o hemoliză intensă sau o contaminare microbiană nu trebuie utilizate pentru testare. Probele de sânge care prezintă semne de liză pot conduce la rezultate neconcludente.

PRECAUŢII

1. Reactivul este destinat exclusiv diagnosticului *in vitro*.
2. Dacă un flacon este crăpat sau curge, aruncaţi conţinutul imediat.
3. Nu folosiţi reactivul după data de expirare (consultaţi **Eticheta flaconului**).
4. Nu folosiţi reactivul dacă observaţi că s-a format un precipitat.
5. Purtaţi echipament de protecţie când manipulaţi reactivul, cum ar fi mănuşi de unică folosinţă şi un halat de laborator.
6. Reactivul a fost filtrat printr-o membrană de 0,2 µm pentru a reduce încărcătura biologică, dar nu este livrat steril. După deschiderea flaconului, reactivul poate fi folosit până la data de expirare dacă nu se observă o turbiditate marcată, care ar putea indica deteriorarea sau contaminarea reactivului.
7. Reactivul conţine <0,1% de azidă de sodiu. Azida de sodiu poate fi toxică dacă este ingerată şi poate reacţiona cu conductele din plumb sau cupru formând azide metalice explozive. La eliminare, spălaţi cu cantităţi mari de apă.
8. Contactul cu LISS împreună cu înălbitorul determină coroziunea accelerată a metalelor de bază, cum ar fi cuprul şi fierul. Ţineţi cont de acest lucru atunci când vă gândiţi să utilizaţi înălbitor pentru decontaminarea conductelor sau aparatelor cu piese metalice, care au venit şi ele în contact cu LISS

ELIMINAREA REACTIVULUI ŞI CUM SE ACŢIONEAZĂ ÎN CAZ DE STROPIRE

Pentru informaţii privind eliminarea reactivului şi metodele de decontaminare a unui loc în caz de stropire, consultaţi **Fişele cu date de securitate ale materialului**, disponibile la cerere.

MARTORI ŞI RECOMANDĂRI

1. Se recomandă testarea a Precise Weak Anti-D Lorne şi a globulelor roşii corespunzătoare (ideal R_1r şi rr) în paralel cu fiecare lot de teste. Testele trebuie considerate nevalide dacă probele martor nu prezintă rezultatele prevăzute.
2. Tehnica antiglobulinică poate fi considerate validă numai dacă toate testele negative reacţionează pozitiv cu globulele roşii sensibilizate cu IgG
3. Soluţia LISS, suspensiile de globule roşii şi serurile de testare trebuie să fie la temperatura camerei înainte de utilizare pentru a se evita unele reacţii pozitive nedorite din cauza anticorpilor „la rece”.
4. În **Tehnici recomandate,** o picătură reprezintă aproximativ 50 µl cu pipeta flaconului furnizată
5. Utilizarea reactivului şi interpretarea rezultatelor trebuie efectuate de personal calificat şi instruit în mod corespunzător în conformitate cu cerinţele ţării în care se utilizează reactivii.
6. Utilizatorul trebuie să stabilească în ce măsură se poate utiliza reactivul în alte tehnici.

REACTIVI ŞI MATERIALE CARE SUNT NECESARE, DAR NU SUNT FURNIZATE

- Antiglobulină umană, adică Lorne AHG Elite (Cat # 435010 sau 415010) sau Anti-IgG umană, adică Lorne Anti-Human IgG (Cat # 401010 sau 402010).
- Spălător de celule Coombs.
- Eprubete de sticlă (10 x 75 mm sau 12 x 75 mm).
- Globule roşii sensibilizate cu IgG, adică Celule de control Coombs Lorne (Cat # 970010).
- Precise Weak Anti-D Lorne (Cat # 209005).
- Soluţie PBS (pH 6,8–7,2) sau soluţie salină izotonă (pH 6,5–7,5).
- Globule roşii martor pozitiv (ideal, R_1r) şi negativ (rr).
- Pipete volumetrice.
- Baie de apă sau incubator cu căldură uscată echilibrate la 37 ºC ± 2 ºC.

TEHNICĂ RECOMANDATĂ

1. Spălaţi globulele roşii cel puţin de două ori în PBS sau soluţie salină izotonă, iar apoi spălaţi-le o dată în LISS „Ready For Use” Lorne.
2. Resuspendaţi globulele roşii la 1,5-2,0% în LISS „Ready For Use”.
3. Amestecaţi bine volume egale de globule roşii suspendate LISS şi ser pentru procedurile LISS, de ex., 2 volume de suspensie de celule 1,5-2% şi 2 volume de ser.

LIMITĂRI

1. Suspensia de globule roşii din LISS este asociată cu o deteriorare accelerată a expresiei antigenelor Fy^a, Fy^b, s şi S, şi, prin urmare, globulele roşii suspendate în LISS trebuie eliminate în cel mult 24 de ore de la pregătire.
2. Pentru integritatea sistemului de testare cu putere ionică joasă, este esenţial să respectaţi raportul volumetric 1:1 dintre suspensia de celule şi ser şi să amestecaţi bine.
3. Pentru sensibilitate optimă, LISS IAT trebuie incubat minimum 15 minute la 37 ºC.
4. Pentru a evita absorbţia nespecifică a complementului autolog, globulele roşii trebuie spălate cel puţin de două ori în NISS înainte de a putea fi spălate în cele din urmă şi resuspendate în LISS.
5. Nu toate reacţiile antigen-anticorp sunt îmbunătăţite prin tehnicile LISS.

CARACTERISTICI DE PERFORMANŢĂ SPECIFICE

1. Înainte de a fi pus pe piaţă, s-a dovedit că fiecare lot de LISS „Ready For Use” Lorne a îmbunătăţit numeroase reacţii antigen-anticorp în cazul utilizării conform **Tehnicilor recomandate.**
2. Soluţia corespunde recomandărilor cuprinse în cea mai recentă ediţie a Guidelines for the UK Blood Transfusion Services (Orientări pentru Serviciile de transfuzii sanguine din Regatul Unit).

DECLINAREA RESPONSABILITĂŢII

1. Utilizatorul este singurul responsabil pentru performanţa reactivului în cazul utilizării altor metode decât cele menţionate în **Tehnici recomandate**.
2. Orice abatere de la **Tehnicile recomandate** trebuie validată înainte de utilizare[10].

BIBLIOGRAFIE

1. Low B., Messeter L. Antiglobulin test in low ionic strength salt solution for rapid antibody screening and crossmatching. Vox. Sang. 1974; **26**. 53-61.
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DIMENSIUNI REACTIV DISPONIBILE

Mărime flacon	Număr de catalog
4x250 ml	470250
20x250 ml	470020
1x2500 ml	470025*

***Această mărime este valabilă numai pentru utilizare de fabricaţie suplimentară (FFMU) şi, prin urmare, nu are marcajul CE.**

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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2017 года № ФСР 2010/08997

На медицинское изделие
Набор контрольных растворов белков мочи "БМ-контроль"
по ТУ 9398-269-52208224-2010

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Медлакор С.-П."
(ООО "Медлакор С.-П."), Россия,
194100, Санкт Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П, офис 212

Производитель
Общество с ограниченной ответственностью "Медлакор С.-П."
(ООО "Медлакор С.-П."), Россия,
194100, Санкт Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П, офис 212

Место производства медицинского изделия
ООО "Медлакор С.-П.", Россия, 194100, Санкт-Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П

Номер регистрационного досье **№ РД-14955/64156 от 20.12.2016**

Вид медицинского изделия **206630**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 11 января 2017 года № 80
допущено к обращению на территории Российской Федерации.

Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0024833

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2017 года № ФСР 2010/08997

На медицинское изделие
Набор контрольных растворов белков мочи "БМ-контроль"
по ТУ 9398-269-52208224-2010:
- комплект 1 «БМ-контроль-ССК»;
- комплект 2 «БМ-контроль-ССК + глюкоза и pH»;
- комплект 3 «БМ-контроль-ССК с калибратором»;
- комплект 4 «БМ-контроль-ССК + глюкоза и pH с калибратором»;
- комплект 5 «БМ-контроль-ПГК»;
- комплект 6 «БМ-контроль-ПГК + глюкоза и pH» .

Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0026953

ИНСТРУКЦИЯ
ПО ПРИМЕНЕНИЮ НАБОРА КОНТРОЛЬНЫХ РАСТВОРОВ БЕЛКОВ МОЧИ + ГЛЮКОЗА и pH
«БМ-контроль-ССК + глюкоза и pH »

Назначение

Набор «БМ-контроль-ССК + глюкоза и pH» предназначен для контроля правильности и воспроизводимости результатов определения в моче :

белков – по их реакции с сульфосалициловой кислотой; с использованием диагностических тест- полосок;

глюкозы – ферментативным методом (глюкозооксидазным); качественным по реакции Бенедикта; с помощью диагностических тест – полосок;

pH – с помощью диагностических тест - полосок.

Набор предназначен только для диагностики in vitro.

Характеристика набора

«БМ-контроль-ССК + глюкоза и pH» представляет собой стабилизированные растворы, содержащие альбумин и глюкозу.

Контрольный материал готов к применению.

Состав набора

Набор «БМ-контроль-ССК + глюкоза и pH» содержит 8 флаконов по 10,0мл контрольных растворов альбумина и глюкозы, по 4 флакона двух уровней концентраций.

В паспорте набора указываются средние значения концентрации белка и глюкозы с контрольными пределами (X±2S).

Условия хранения и эксплуатации

Набор «БМ-контроль-ССК + глюкоза и pH» хранится при температуре (2 – 8) ^{o}C в темном месте.

Срок годности 9 месяцев.

В распечатанных и закрытых пробкой флаконах контрольный раствор белков мочи хранится при температуре (2 – 8) ^{o}C не более 14 дней.

. Меры предосторожности

При работе с набором необходимо соблюдать общие правила техники безопасности и производственной санитарии в клинико- диагностической лаборатории.

Аналитические характеристики

Диапазоны концентраций:

Белок	(0,2 - 0,4) г/л;
Глюкоза	(1,5 – 6,5) ммоль/л

Коэффициенты вариации:

Белок	не более 10%;
Глюкоза	неболее 5%.

Оборудование

Фотометр, кюветы с толщиной слоя 5 мм

Биохимический анализатор

Применение контрольных растворов

Контрольные растворы применяют в тех же условиях и с теми же реагентами, что и анализируемые образцы мочи.

Перед использованием флаконы с контрольными растворами выдерживают при комнатной температуре в течение 15 мин, затем перемешивают вручную путем переворачивания флакона 5-6 раз.

Определение концентраций компонентов проводят в соответствии с инструкциями к наборам реагентов или по методикам, утверждённым конкретным медицинским учреждением.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture and distribution of laboratory diagnostic, clinical diagnostic and rapid tests (see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-12-02
Certificate Registration No.:	SX 60131401 0001
An audit was performed. Report No.:	21200072 015
This Certificate is valid until:	2021-12-01

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-11-27

Dipl.-Ing. Sven Hoffmann

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TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60131401 0001
Report No.: 21200072 015

Organization:
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Scope:

Sites included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg, Germany

Activities: Design, development and distribution

nal von minden GmbH
Robert-Bosch-Breite 23
37079 Göttingen, Germany

Activities:
Design, development, manufacture and distribution

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131398 0001

Report No.: 21200072 015

Manufacturer:
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products:
- IVDs for the detection of infectious disease markers
- IVDs for the detection of the tumor marker PSA
- Urine tests for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60114562 0001

Expiry Date: 2023-11-27

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Notified Body

Effective Date: 2018-11-28

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60131398 0001
Report No.: 21200072 015

Manufacturer:
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products included:

In vitro diagnostica for self-testing:
- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis

In vitro diagnostica rapid tests:
- Chlamydia trachomatis Rapid Tests
- PSA Rapid Tests

Site included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg
Germany

Activities: Design and development

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

Certificate Holder: **nal von minden GmbH**
Carl-Zeiss-Str. 12
47445 Moers
Germany

including the locations according to annex

Scope: Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.
Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2021-09-10 until 2024-09-09.
First certification 2018

2021-09-10

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

No.	Location	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development, distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

2021-09-10

TÜV Rheinland Cert GmbH
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NADAL® FOB Test

(test cassette) REF 272001

Instructiune de folosire

1. Destinația utilizării

Testul NADAL® FOB este o imunotestare rapidă, vizibilă pentru determinarea calitativă, prezumtivă a hemoglobinei umane în probele de fecale. Testul este destinat utilizării ca ajutor pentru diagnosticarea patologiilor gastro-intestinale inferioare (g.i.). Testul este conceput numai pentru uz profesional.

2. Introducere și semnificație clinică

Cancerul colorectal este unul dintre cele mai frecvent diagnosticate tipuri de cancer și o cauză principală a deceselor legate de cancer. Screeningul pentru sângele ocultic în materiile fecale este posibil să îmbunătățească șansele de detectare a cancerului colorectal într-un stadiu incipient, reducând astfel mortalitatea. Anterior, testele FOB disponibile în comerț au utilizat metoda Guaiac, care necesită o dietă specială înainte de testare pentru a evita rezultatele fals pozitive și false negative.
Testul **NADAL® FOB** este conceput pentru a detecta hemoglobina umană în mostre fecale. Testul se bazează pe o metodă imunochemică care îmbunătățește specificitatea detectării tulburărilor gastro-intestinale inferioare, incluzând cancerele colorectale și adenomii fără restricții alimentare

3. Principiul de testare

Testul **NADAL® FOB** este utilizat pentru a detecta hemoglobina umană prin interpretarea vizuală a dezvoltării de culoare pe banda internă. Anticorpii la hemoglobina umana sunt imobilizat în regiunea liniei de test a membranei. În timpul testării, eșantionul reacționează cu anticorpi la hemoglobina umană conjugată cu particule colorate și preacoperită pe tamponul de probă al testului. Apoi, amestecul migrează de-a lungul membranei prin acțiunea capilară și interacționează cu componentele membranei. Dacă este suficient hemoglobină umană din specimen, se va forma o linie colorată în regiunea liniei de testare a membranei. Prezența acestei linii colorate indică un rezultat pozitiv al testului, în timp ce absența acestuia indică un rezultat negativ al testului. Apariția unei linie colorat în regiunea liniei de control servește ca un control procedural indicând faptul că volumul corespunzător al specimenului a fost adăugat și a avut loc răni de membrană.

4. Reactivi și materiale furnizate

Fiecare set de testare este potrivit pentru 20 de evaluări ale testelor:
• 20 casete de testare înfășurate individual;
• 20 tuburi de colectare a probelor cu tampon diluant pentru probe;
• 1 prospect;

5. Materiale suplimentare necesare

• Timer;
• Colector de scaun (mase fecale);
• Blocul de informare a pacientului cu instrucțiuni scurte privind colectarea specimenelor de scaun(mase fecale).
• Container de colectare a probelor (opțional, dacă este necesar un eșantion de scaun nediluat și etapa de diluare este efectuată doar imediat înainte de testare)

6. Stocare și stabilitate

Testul trebuie păstrat la 2-30 ° C până la data de expirare tipărită pe folia sigilată. Testul trebuie să rămână în punga sigilată până la utilizare. Nu îngheață testul. Trebuie să se ia măsuri pentru a proteja componentele kitului de testare de la contaminare. Nu utilizați testul dacă există dovezi ale contaminării microbiene sau ale precipitațiilor. Contaminarea biologică a echipamentului de distribuire, a recipientelor sau a reactivilor poate duce la rezultate inexacte.

7. Avertismente și precauții

• Pentru utilizare profesională in vitro numai pentru diagnostic. • Pentru o singură utilizare. • Nu utilizați testul după data expirării indicată pe husă de folie. • Nu utilizați testul dacă punga folie este deteriorată. • Testul conține produse de origine animală. Cunoașterea științifică a stării de origine și / sau starea sanitară a animalelor nu garantează în totalitate absența agenților patogeni transmisibili. Se recomandă testele să fie tratate ca potențial infecțioase și tratate prin respectarea măsurilor de siguranță obișnuite (de exemplu, nu ingerați și nu inhala). • Evitați contaminarea încrucișată a probelor utilizând un nou tub de colectare pentru fiecare probă. • Înainte de testare, citiți cu atenție întregul insert. • Nu mâncați, nu beți și nu fumați în zona în care se manipulează specimenele și trusele de testare. • Manipulați toate probele ca și când acestea conțin agenți infecțioși. Respectați precauțiile stabilite împotriva pericolelor microbiologice pe toată durata procedurii și urmați procedurile standard pentru evacuarea corespunzătoare a probelor. • Purtați îmbrăcăminte de protecție, cum ar fi blănuri de laborator, mănuși de unică folosință și protecția ochilor atunci când eșantioanele sunt testate. • Tamponul diluant al probelor conține azidă de sodiu care poate reacționa cu instalațiile de plumb sau cupru pentru a forma azide metalice potențial explozive. Atunci când eliminați eșantioanele tampon diluant sau probele extrase, întotdeauna spălați cu cantități mari de apă pentru a preveni acumularea de azide. • Aduceți toți reactivii la temperatura camerei (15-30 ° C) înainte de utilizare. • Nu adăugați nicio soluție în zona de reacție (zona de rezultat). • Pacienții nu trebuie să colecteze probe în timpul perioadei menstruale sau cu 3 zile înainte și după aceasta sau dacă au hemoroizi hemoragici, sânge în urină sau dacă au suferit în timpul deplasării intestinului. • Nu înlocuiți și nu

amestecați componente din kituri de testare diferite. • Umiditatea și temperaturile înalte pot afecta negativ rezultatele testelor. • Materialele de testare utilizate trebuie aruncate în conformitate cu reglementările locale.

8. Colectarea și prepararea probelor

Depozitați eprubeta de colectare a probelor la temperatura camerei. Se recomandă colectarea specimenului de scaun folosind un colector de scaune. Evitați diluarea probelor de scaun cu urină sau apă din vasul toaletei.

1. Țineți tubul de colectare a probei în poziție verticală și scoateți capacul albastru deschis. Scoateți banda aplicatorului (tija spirală). Aveți grijă să nu vărsați soluția tampon din tubul de colectare.
2. Colectați specimenele prin introducerea stick-ului aplicator în trei locuri diferite ale probei scaunului.

Notă: Asigurați-vă că ați introdus stick-ul aplicatorului de trei ori la rând în proba scaunului. NU puneți aplicatorul înapoi în tub între colectarea celor 3 probe. Aveți grijă să nu vărsați lichid din tub. Natura eșantionului și respectarea acestor instrucțiuni vor afecta rezultatul testului.

3. Așezați stick-ul aplicatorului, împreună cu proba, înapoi în tubul de colectare a probei și închideți-l corespunzător.
4. Agitați viguros tubul de colectare a probelor pentru a amesteca eșantionul și tamponul diluant al probelor.

Notă:

Testul **NADAL® FOB** este destinat utilizării numai cu eșantioane de fecale umane. Pacienții nu trebuie să colecteze eșantioane în timpul perioadei menstruale sau cu 3 zile înainte și după aceasta sau dacă acestea au hemoroizi hemoragici, sânge în urină sau dacă suferă tulpină în timpul deplasării intestinului.

Alcoolul, aspirina și alte medicamente administrate în exces pot provoca iritații gastro-intestinale, ducând la sângerări oculte. Aceste substanțe trebuie întrerupte cu cel puțin 48 de ore înainte de testare.

Nu sunt necesare restricții alimentare înainte de testare.

Efectuați testul cât mai curând posibil după colectarea probelor.

Nu lăsați specimenele la temperatura camerei pentru perioade prelungite de timp. În ansamblu, timpul de păstrare a probelor la 2-8 ° C nu trebuie să depășească 7 zile. Transportul eșantioanelor la clinică pot fi efectuate la temperatura camerei fără probleme; totuși nu ar trebui să depășească 2 ore. Aduceți eșantioanele la temperatura camerei înainte de testare.

9. Procedura de testare

1. Aduceți casetele de testare și mostrele pacientului (probe extrase) la temperatura camerei (15 ° C până la 30 ° C) înainte de testare.
2. Scoateți o casetă de testare din punga de folie etanșă și așezați-o pe o suprafață curată și plană. Etichetați caseta de testare cu un identificator al pacientului sau de control. Pentru cele mai bune rezultate, analiza trebuie efectuată în decurs de o oră.
3. Se agită tubul de colectare a probelor pentru a asigura buna amestecare a proba de fecale cu eșantioanele tampon de diluare.
4. Deșurubați capacul de protecție alb din eprubeta de colectare a probelor. Folosind o bucată de hârtie absorbantă, rupeți vârful tubului de colectare utilizând o mișcare de răsucire.
5. Țineți tubul de colectare a probei în poziție verticală și eliberați 3 picături de soluție în galeria de probă (S) a casetei de testare. Evitați blocarea bulelor de aer în fanta de probă (S) și nu adăugați nicio soluție în zona rezultată.
6. Citiți rezultatul după 5 minute. Nu interpretați rezultatele după mai mult de 10 minute.

10. Interpretarea rezultatelor

Pozitive:

Două linii colorate apar pe membrană. Pe linia de control (C) și pe cealaltă apare o linie în regiunea liniei de testare (T).

Negativ:

Pe rând apare o singură linie colorată regiunea de control (C). Fără linie colorată apare în regiunea liniei de testare (T).

Invalid:

Linia de control (C) nu apare.

Rezultatele obținute din orice încercare care nu a produs o linie de control la timpul specificat de lectură trebuie eliminate. Examinați procedura și repetați testul cu o nouă casetă de testare. Dacă problema persistă, întrerupeți imediat utilizarea setului de testare și contactați distribuitorul.

Notă:

intensitatea culorii în regiunea liniei de testare (T) poate varia în funcție de concentrația de analiți prezenți în eșantion. Prin urmare, orice nuanță de culoare din regiunea liniei de testare trebuie considerată pozitivă. Rețineți că acesta este doar un test calitativ și nu poate fi utilizat pentru a determina concentrația de analiți din specimen. Volumul specimenului insuficient, procedura de operare incorectă sau testele expirate sunt motivele cele mai probabile pentru eșecul liniei de control.

11. Controlul calității

Un control procedural intern este inclus în caseta de testare.

O linie colorată care apare în regiunea liniei de control (C) este considerată un control intern procedural pozitiv, confirmând volumul suficient al specimenului și tehnica procedurală corectă.

Cu toate acestea, atunci când eșantionul de fecale este testat, fundalul poate părea ușor gălbui din cauza culorii originale a probei. Acest lucru este acceptabil atâta timp cât nu interferează cu interpretarea rezultatului testului. Testul este nevalid dacă fundal nu reușește să clarifice și să ascundă citirea rezultatului.

12. Limitări

• Testul **NADAL® FOB** este destinat exclusiv utilizării de diagnosticare in vitro. Ar trebui folosit numai pentru detectarea calitativă a hemoglobinei umane.
• Prezența sângelui în probele de scaun se poate datora altor cauze decât sângerarea colorectală, cum ar fi hemoroizii, sânge în urină sau iritație la nivelul stomacului.
• Rezultatele negative nu exclud sângerarea, deoarece unele polipi și cancerele colorectale din regiune pot sângera intermitent sau deloc. În plus, sângele poate să nu fie distribuit uniform în probele de fecale și în polipii colorectali într-o perioadă precoce nu pot sângera.
• Urina și diluția excesivă a probelor cu apă de toaletă pot determina rezultate eronate.
• Testul **NADAL® FOB** poate indica sensibilitate scăzută la sângerarea gastrointestinală superioară, deoarece sângele se degradează pe măsură ce trece prin tractul gastro-intestinal.
• Nu toate sângerările colorectale se datorează polipilor precanceroși sau canceroși. Ca și în cazul tuturor testelor diagnostice, un diagnostic confirmat trebuie făcut numai de către medic după ce toate evaluările clinice și de laborator au fost evaluate.

13. Caracteristicile de performanță

Sensibilitatea analitică
Specimene care conțin hemoglobină umană cu o concentrație egală sau mai mare de 40 ng / ml produc rezultate pozitive. În unele cazuri care conțin hemoglobină umană cu concentrații mai mici de 40 ng / ml pot produce, de asemenea, rezultate pozitive.

Efect de cârlig sau de prozonă:
Intervalul de lucru al testului **NADAL® FOB** este de 2 µg / g până la 25 mg / g fecale (= 40 ng / ml până la 500000 ng / ml). La nivel superior concentrații, testul arată un "efect înalt Hook sau Prozone". În cazul unui presupus efect de cârlig, diluați eșantionul și repetați măsurarea.

Specificitatea analitică:
Testul **NADAL® FOB** este specific pentru hemoglobina umană și nu prezintă reacții încrucișate cu hemoglobină din sângele bovin, curcan, porc, iepure, pui, cal și capre la concentrații de până la 1 mg / ml.

Substanțe interferante
Testul **NADAL® FOB** nu prezintă reacții încrucișate cu cele enumerate substanțe:

analiți	*concentratia*		*analiți*	*concentratia*
Ascorbic acid	20 mg/dL		Urea	2000 mg/mL
Oxalic acid	60 mg/dL		Glucose	2000 mg/dL
Bilirubin	100 mg/dL		Caffeine	40 mg/dL
Uric acid	60 mg/dL		Albumin	2000 mg/dL
Acetylsalicylic acid	20 mg/dL			

		NADAL® FOB Test		
Alt test rapid		+	-	total
	+	325	9	334
	-	16	1024	1040
	total	341	1033	1374

Sensibilitate relativă:97,3% (95,56% -99,04%) *
Specificitatea relativă:98,4% (97,64% -99,16%) *
Acord general:98,2% (97,47% -98,89%) *
* Interval de încredere de 95%

Notă: Un studiu publicat recent de Școala Shinshu-Universitate din Medicina din Japonia a examinat raportul cost-valoare al multiplelor Măsurători. Aceasta arată că sensibilitatea relativă crește cu cantitatea de teste și specificitatea relativă a acesteia ușor scade.

Numărul de teste	*sensibilitatea*	*specificitatea*
1	*58%*	*96%*
2	*89%*	*95%*
3	*100%*	*94%*

Notă: această instrucţie se va utiliza paralel cu instrucţia originară din cutia kitului primită de la producător.

EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

Manufacturer: nal von minden GmbH, Carl-Zeiss Str.12, 47445 Moers
Classification: Other Products

We herewith declare on our sole responsibility that all batches of below mentioned In-vitro-diagnostic devices are conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The products are suitable for the intended application (only professional users).

Relevant standards and guidelines are applied.

141000	NADAL® EARLY hCG Pregnancy dipstick
141000_SSL	NADAL® EARLY hCG Pregnancy dipstick
141002	NADAL® hCG Pregnancy Test 25 mIU/ml dipstick
142000	NADAL® EARLY hCG 10 mIU/ml cassette
142002	NADAL® hCG Pregnancy Cassette Test 25 mIU/ml
143003	NADAL® hCG Pregnancy Tests 10 mIU/ml dipstick
143004	NADAL® hCG t 25 mIU/ml dipstick
143004_SSL	NADAL® hCG t 25 mIU/ml dipstick
144001N-10	NADAL® hCG Pregnancy Test, Midstream 20 mIU/ml cassette
151002	NADAL® hCG Pregnancy
151002SE	NADAL® hCG Pregnancy rapid test
151003	NADAL® hCG Test 10mIU/ml Urin/Serum Dipstick
152000	NADAL® hCG Pregnancy 10 mIU/ml cassette
152002	NADAL® hCG Pregnancy 25 mIU/ml cassette
152003	NADAL® hCG Pregnancy Test 20 mIU/ml cassette S/P/W

153002	NADAL® hCG Pregnancy TEST 10 mIU/ml – Urin/Serum
153003	NADAL® hCG 25 mIU/mln Dipstick
153003_SSL	NADAL® hCG 25 mIU/mln Dipstick
161001	NADAL® hLH Ovulation rapid test
161001_SSL	NADAL® hLH Ovulation rapid test
162001	NADAL® hLH Ovulation rapid test
162001_SSL	NADAL® hLH Ovulation rapid test
164001	NADAL® hLH Ovulation 30 mIU/ml Midstream
165001	NADAL® hLH Ovulation 30 mIU/ml dipstick
165001_SSL	NADAL® hLH Ovulation 30 mIU/ml dipstick
165002	NADAL® hLH Ovulation rapid tests (2,5mm)
165003	NADAL® hLH Ovulation rapid test
165003_SSL	NADAL® hLH Ovulation rapid test
166001	NADAL® hLH Ovulation 30 mIU/ml cassette
172001	NADAL® FSH cassette
172001_SSL	NADAL® FSH cassette
172003N-10	NADAL® FSH cassette
194002	NADAL® pH-Test

201001	NADAL® Syphilis dipstick
201001_SSL	NADAL® Syphilis dipstick
202001	NADAL® Syphilis cassette
202001_SSL	NADAL® Syphilis cassette
203001	NADAL® Syphilis rapid tests
203002	NADAL® Syphilis rapid tests
203002_SSL	NADAL® Syphilis rapid tests
221001A	NADAL® Strep A dipstick
221005	NADAL® Strep A reagent 1
221006	NADAL® Strep A reagent 2
221050N-50	NADAL® Strep A plus rapid tests
222001A	NADAL® Strep A cassette
222007	NADAL® Strep A plus cassette
222008	NADAL® Strep A plus cassette
222011	NADAL® Strep A plus cassette
222049BUL	NADAL® Strep A Scan cassette
222049BUL-20	NADAL® Strep A Scan cassette
232001	NADAL® Strep B cassette
232001_SSL	NADAL® Strep B cassette
232005	NADAL® Strep B reagent 1
232006	NADAL® Strep B reagent 2
241005N-10	NADAL® Influenza A+B dipstick
241006N-25	NADAL® Influenza A+B dipstick
242001	NADAL® Influenza A+B cassette
242006N-10	NADAL® Influenza A/B cassette
252001	NADAL® Mononucleosis cassette
252002	NADAL® Mononucleosis dipstick
252003	NADAL® Mononucleosis cassette
252003N-20	NADAL® Mononucleosis cassette
252005	NADAL® Mononucleosis positive conrtol
252006	NADAL® Mononucleosis negative conrtol
252017N-05	NADAL® Mononucleosis cassette
262001	NADAL® H.Pylori Antikörper cassette
262001_SSL	NADAL® H.Pylori Antikörper cassette
262002	NADAL® H.Pylori Antigen cassette
262003	NADAL® H. pylori Ab cassette
262004BUL	NADAL® H. pylori Scan Ab cassette
262004BULN-10	NADAL® H. pylori Scan Ab cassette
272001	NADAL® FOB cassette
272001_SSL	NADAL® FOB cassette
272008	NADAL® FOB cassette
272009	NADAL® Hb/Hp Complex cassette
272010	NADAL® FOB cassette
272011	NADAL® Hb/Hp cassette
272011N-25	NADAL® Hb/Hp cassette
272015	NADAL® Hb/Hp Complex cassette
272015_SSL	NADAL® Hb/Hp Complex cassette
272016	NADAL® FOB plus cassette
272031RU	NADAL® Hb/Hp Complex cassette
272031RU-01	NADAL® Hb/Hp Complex cassette
272031RU_SSL	NADAL® Hb/Hp Complex cassette
272035	NADAL® FOB60 plus cassette
272035_SSL	NADAL® FOB60 plus cassette
272037	NADAL® FOB & Hb/Hp patient set
272040	NADAL® FOB II Cassettes
272041	NADAL® FOB60 Cassette
272041_SSL	NADAL® FOB60 Cassette
272042	NADAL® FOB75 Cassette
272043	NADAL® FOB75 II Cassette
282000	NADAL® Troponin I cassette
282001	NADAL® Troponin I cassette
282001_SSL	NADAL® Troponin I cassette
282003	NADAL® Trop I, CK-MB, Myoglobin Combi- cassette
282015	NADAL® Troponin I cassette
292001	NADAL® Myoglobin cassette
292001N-05	NADAL® Myoglobin cassette

302001	NADAL® CK-MB cassette
302001_SSL	NADAL® CK-MB cassette
311003	NADAL® CrP Dipstick
311004	NADAL® CRP plus Dipstick
311006	NADAL® CRP plus Dipstick
312001	NADAL® CrP cassette
312002	NADAL® high sensitive CrP cassette
312017	NADAL® CRP Quant RFID chip
312021BUL	NADAL® CRP Quant cassette
312021NBUL-20	NADAL® CRP Quant cassette
322003N-30	NADAL® Tuberkulose IgG/IgM cassette
322003N-30_SSL	NADAL® Tuberkulose IgG/IgM cassette
331001	NADAL® Mikroalbumin Dipstick
331004N-50	NADAL® Mikroalbumin Dipstick
333001	NADAL® Mikroalbumin Dipstick
351006	NADAL® D-Dimer cassette
351006_SSL	NADAL® D-Dimer cassette
351007	NADAL® D-Dimer cassette
374018	qLabs aPTT-INR Control
431001N-03	NADAL® PROM Test Dipstick
431001N-03_SSL	NADAL® PROM Test Dipstick
431001N-10	NADAL® PROM Test Dipstick
431001N-10_SSL	NADAL® PROM Test Dipstick
431001N-20	NADAL® PROM Test Dipstick
431006N-03	NADAL® PROM Amniotic fluid Dipstick
431006N-10	NADAL® PROM Amniotic fluid Dipstick
431006N-20	NADAL® PROM Amniotic fluid Dipstick
472001N-25	NADAL® Malaria Pf Ag test cassette
472001N-25_SSL	NADAL® Malaria Pf Ag test cassette
472003N-25	NADAL® Malaria 4 species cassette
472003N-10	NADAL® Malaria 4 species cassette
472003_SSL	NADAL® Malaria 4 species cassette
472008	NADAL® Malaria 4 species cassette
472009	NADAL® Malaria Pf/Pv Ab cassette
472030N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
472030N-10	NADAL® Malaria Pf/Pan Ag 4Species cassette
472036N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
481002	NADAL® Adenovirus rapid tests
481003	NADAL® Adenovirus rapid tests
481004	NADAL® Rotavirus rapid tests
481005	NADAL® Rotavirus rapid tests
481006	NADAL® Adenovirus 40/41 strips
481007	NADAL® Adenovirus 40/41 strips
481008	NADAL® Adenovirus Respiratory rapid tests
481013	Adenovirus Positive Control
481015	NADAL® Rota-Adenovirus cassette
481015_SSL	NADAL® Rota-Adenovirus cassette
481015N-20	NADAL® Rota-Adenovirus cassette
481016	NADAL® Adenovirus cassette
481016_SSL	NADAL® Adenovirus cassette
481017	NADAL® Rotavirus cassette
481049BUL	NADAL® Rota-Adenovirus Scan cassette
481049BUL-10	NADAL® Rota-Adenovirus Scan cassette
491000N-10	NADAL® RSV plus Dipstick
491000N-10_SSL	NADAL® RSV plus Dipstick
491003N-25	NADAL® RSV Dipstick
491005	NADAL® RSV cassette
491008BUL	NADAL® RSV Scan cassette
491009	NADAL® RSV-Adeno Resp cassette
491015	NADAL® RSV Dipstick
495001	NADAL® MRSA Screen Latex-Agglutinationstest

495001_SSL	NADAL® MRSA Screen Latex-Agglutinationstest
501006	NADAL® *E.coli* O157 Cassette
501006_SSL	NADAL® *E.coli* O157 Cassette
501012	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
501012_SSL	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
511002	NADAL® Cryptosporidium Dipstick
511006	NADAL® Cryptosporidium cassette
511006_SSL	NADAL® Cryptosporidium cassette
521001	NADAL® Giardia Dipstick
521004	NADAL® Crypto/Giardia Test strips
521006	NADAL® Giardia cassette
521009	NADAL® Giardia cassette
521010	NADAL® Giardia-Crypto-Combo cassette
521010_SSL	NADAL® Giardia-Crypto-Combo cassette
532001_SSL	NADAL® Dengue cassette
532001N-25	NADAL® Dengue cassette
532002N-25	NADAL® Dengue cassette
532003N-25	NADAL® Dengue cassette
532004N-25	NADAL® Dengue cassette
532004N-25_SSL	NADAL® Dengue cassette
532011	NADAL® Dengue IgG/IgM cassette
532011N-25	NADAL® Dengue IgG/IgM cassette
532012N-25	NADAL® Dengue NS1 Ag Cassette
532016N-25	NADAL® Dengue NS1 Ag+IgG/IgM Cassette
542001N-25	NADAL® Tetanus cassette
552005	NADAL® Legionella Urin Antigen cassette
552005_SSL	NADAL® Legionella Urin Antigen cassette
552006	NADAL® Legionella Urin Antigen cassette
552006_SSL	NADAL® Legionella Urin Antigen cassette

552020	NADAL® Legionella Urine Antigen test
562003N-10	NADAL® BCA/HB inkl.
562003RU	NADAL® BCA/HB inkl.
572004N-10	NADAL® Streptococcus pneumoniae cassette
572005	NADAL® Legionella/S. pneumonia cassette
580005N-25	NADAL® TSH cassette
582003	NADAL® C. difficile Toxin A/B cassette
582003_SSL	NADAL® C. difficile Toxin A/B cassette
582004	NADAL® Clostridium Difficile GDH
582008	NADAL® Clostridium Difficile Toxins A&B cassette
582009	NADAL® C. perfringens Ag cassette
582009_SSL	NADAL® C. perfringens Ag cassette
582016N-10	NADAL® Clostridium Difficile Toxin A+B/GDH Cassette
600002N-30	NADAL® Rheumatoid Factor test cassette
611003N-10	NADAL® Gonorrhea cassette
611003N-10_SSL	NADAL® Gonorrhea cassette
611005N-10	NADAL® Gonorrhea cassette
612004N-25	NADAL® CCA (Bilharzia) cassette
622001N-30	NADAL® HAV IgM test cassette
622040N-30	NADAL® HEV IgM cassette
622070N-30	NADAL® HAV IgG/IgM cassette
622070N-30_SSL	NADAL® HAV IgG/IgM cassette
652001N-30	NADAL® Chagas IgG cassette
652001N-30_SSL	NADAL® Chagas IgG cassette
662001N-30	NADAL® Leishmania cassette
672001N-30	NADAL® Filariasis cassette
672001N-30_SSL	NADAL® Filariasis cassette
682002N-20	NADAL® Chikungunya IgM Cassette

692001N-30	NADAL® Typhus Cassette
692001N-30_SSL	NADAL® Typhus Cassette
712001	NADAL® AFP Cassette
712001_SSL	NADAL® AFP Cassette
722003	NADAL® CEA Cassette
722003_SSL	NADAL® CEA Cassette
790001	NADAL® Celiac Disease tTG Cassette
790001_SSL	NADAL® Celiac Disease tTG Cassette
790002	NADAL® Celiac Disease tTG & Gliadine Cassette
795002	NADAL® ASO Latex
795003	NADAL® ASO Latex
795005	NADAL® CRP Latex
795006	NADAL® CRP Latex
795008	NADAL® RF Latex
795008_SSL	NADAL® RF Latex
795009	NADAL® RF Latex
795010	NADAL® RPR Carbon Latex
795011	NADAL® RPR Latex
795015	NADAL® VDRL
795016	NADAL® VDRL
795017	NADAL® Waaler Rose Latex
795018	NADAL® Waaler Rose Latex
795024	NADAL® IM Latex
795027	NADAL® TPHA
795028	NADAL® TPHA
795030	NADAL® Rose Bengale
850003	NADAL®Astrovirus Test Cassette
850003N-10	NADAL®Astrovirus Test Cassette
860001	NADAL® Bence Jones Proteinurie Dipstick

870001	NADAL® Lyme Borreliose Cassette
920001	NADAL® Norovirus Cassette
920001_SSL	NADAL® Norovirus Cassette
920002	NADAL® Norovirus I+ II Cassette
920002_SSL	NADAL® Norovirus I+ II Cassette
1010002N-20	NADAL® Cholera O1/O139 cassette
1120003N-20	NADAL®Candida Albicans (Cassette á 20)
1130002N-30	NADAL® HSV-1 IgG/IgM - Herpes-Simplex-Virus
1130003N-30	NADAL®HSV-2 IgG/IgM - Herpes-Simplex-Virus
1200001	NADAL® Lactoferrin – Test – Feces (Cassette á 10)
1201004N-10	NADAL® Ferritin cassette
1212001	NADAL® Calprotectin – Test – Feces (TK á 10)
1212001_SSL	NADAL® Calprotectin – Test – Feces (TK á 10)
1212002	NADAL® Calprotectin +Lactoferrin Test Feces (TK á 10)
1222001	NADAL® Enterovirus – Test – Feces (TK á 10)
1222001_SSL	NADAL® Enterovirus – Test – Feces (TK á 10)
1232001	NADAL® Campylobacter – Test – Feces (TK á 10)
1242001	NADAL® Salmonella spp. – Test – Feces (TK á 10)
1242002	NADAL® Salmonella Typhi-Test – Feces (TK á 10)
1252001	NADAL® Listeria-Test – Feces (TK á 10)
1262001	NADAL® Shigella-Test - Feces (TK à 10)
1262002	NADAL® Shigella Dysenteriae-Test – Feces (TK à 10)
1320002	NADAL® HB Hämoglobin Dipstick (á 50)

1320003	NADAL® HB Kontroll Dipstick (á 2)
1320004	NADAL® HB Kapillarröhrchen 10 µl (á 50)
2090001	NADAL® Entamoeba cassette
2090001_SSL	NADAL® Entamoeba cassette
2200001	NADAL® IgG cassette
2201001N-10	NADAL® IgE cassette
2210001	NADAL® IgE cassette
2210001_SSL	NADAL® IgE cassette

This document is valid until 23.03.2019.

Moers, 24.03.2017
nal von minden GmbH

Sandra von Minden
CEO
nal von minden GmbH

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ICIM

CERTIFICATO n.
CERTIFICATE No. **4265/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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ICIM

CERTIFICATO n.
CERTIFICATE No. **4264/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

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Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
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0449CM_03_IT

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
59878-2009-AQ-MCW-FINAS

Initial certification date:
20 December 2000

Valid:
01 September 2021 – 31 August 2024

This is to certify that the management system of

THERMO FISHER SCIENTIFIC

Kubinskaya 73, liter A, build.1, Saint-Petersburg, Russian Federation, 196240

has been found to conform to the Quality Management System standard:

ISO 9001:2015

This certificate is valid for the following scope:

MANUFACTURING OF LIQUID HANDLING PRODUCTS AND SPECIAL DIAGNOSTIC PLASTICS.

Place and date:
Espoo, 18 June 2021

For the issuing office:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ОПИСАНИЕ ДОЗАТОРА

Дозатор пипеточный Ленпипет Лайт представляет собой дозатор для забора и дозирования точных объемов жидкости. Он работает по принципу воздушного вытеснения (т. е. между плунжером и жидкостью имеется объем воздуха) в одноразовом сменном наконечнике.

Существует девять моделей одноканальных дозаторов фикированного объема Ленпипет Лайт.

Кат.	Объем	Наконечник
4650002	1 мкл Микро	10
4650012	5 мкл Микро	10
4650022	10 мкл	250 Унив., 200 Удл., 300
4650092	20 мкл	250 Унив., 200 Удл., 300
4650032	25 мкл	250 Унив., 200 Удл., 300
4650042	50 мл	250 Унив., 200 Удл., 300
4650052	100 мкл	250 Унив., 200 Удл., 300
4650062	200 мкл	250 Унив., 300
4650062	250 мкл	250 Унив., 300
4650072	500 мкл	1000
4650082	1000 мл	1000

ЦИФРОВАЯ ИНДИКАЦИЯ

Объем дозирования указан на цифровом дисплее на рукоятке дозатора (рис.1).

Рис. 1

КОНСТРУКТИВНЫЕ МАТЕРИАЛЫ

Дозаторы Ленпипет Лайт изготавливаются из материалов высокой механической и химической стойкости.

НАКОНЕЧНИКИ

Для работы дозаторов Ленпипет Лайт рекомендуется использовать наконечники Ленпипет и Finntip. Они изготовлены из чистого обесцвеченного полипропилена, который считается материалом свободным от контаминации и прекрасно подходит для изготовления наконечников.

Кат. №№	Объем	Количество
9400310	0.2-10 мкл	1000 шт./уп
9400360	0.2-50 мкл	1000 шт./уп.
9401262	0.5-250 мкл	96 шт./штатив
9400267	0.5-250 мкл	20*96 шт. в башне
9400302	0.5-250 мкл	1000 шт./уп.
9400242	0.5-250 мкл	20000 шт./кор.
9401260	5-300 мкл	1000 шт./уп
9401282	100-1000 мкл	96 шт./штатив
9401032	100-1000 мкл	1000 шт./уп.
9401022	100-1000 мкл	5000 шт./кор.

ЭКСПЛУАТАЦИЯ ПИПЕТКИ

ЯРЛЫК БЕЗОПАСНОСТИ

На место ярлыка безопасности можно нанести необходимую Вам информацию, например, фамилию или дату последней поверки дозатора (рис.3)


Рис. 3

СБРОС НАКОНЕЧНИКА

Чтобы исключить риск контаминации, каждый дозатор Ленпипет Лайт имеет специальный механизм для сброса наконечника. Чтобы сбросить наконечник, направьте дозатор на резервуар для отходов и нажмите на удалитель наконечника большим пальцем (рис. 4).


Рис. 4

ТЕХНИКА ДОЗИРОВАНИЯ

Всегда нажимайте и отпускайте операционную кнопку плавно, особенно при работе с растворами высокой вязкости. Никогда не отпускайте кнопку резко при обратном движении.

Убедитесь, что наконечник плотно держится на посадочном месте. Проверьте, нет ли на наконечнике посторонних частиц. Перед началом работы наполните и опустошите наконечник 2-3 раза раствором, с которым Вы собираетесь работать. Удерживайте дозатор в строго вертикальном положении при наборе реагента. Упор на дозаторе должен опираться на указательный палец. Убедитесь, что температура дозатора, наконечников и раствора одинакова.

ПРЯМОЙ МЕТОД (рис. 5)

Наполните чистую ванночку для реагента раствором для раскапывания.

Рис. 5

1. Нажмите на операционную кнопку до первой остановки.

2. Погрузите наконечник в раствор примерно на глубину 1 см и плавно отпустите кнопку. Извлеките наконечник, аккуратно снимая излишки раствора о край резервуара.

3. Дозируйте взятый раствор, плавно нажимая на кнопку до первой остановки. После примерно секундной паузы нажмите операционную кнопку до второй остановки. После выполнения данной операции наконечник должен полностью опустошиться.

4. Отпустите кнопку в исходное положение. Если необходимо, смените наконечник и продолжайте пипетирование.

ОБРАТНЫЙ МЕТОД (рис. 6)

Обратный метод используется для работы с жидкостями, имеющими высокую вязкость или склонность к вспениванию, а также данная техника рекомендуется для раскапывания очень малых объемов. Наполните чистую ванночку для реагента раствором для раскапывания.

Рис. 6

1. Держа дозатор вертикально, нажмите операционную кнопку до второй остановки.

2. Погрузите наконечник примерно на 1 см в глубину раствора и плавно отпустите кнопку. Наконечник наполняется. Извлекая наконечник, аккуратно снимите излишки раствора о край резервуара.

3. Дозируйте раствор, нажимая на кнопку до первой остановки. Удерживайте кнопку на первой остановке. Немного раствора останется в наконечнике. Этот остаток раствора не должен включаться в дозируемый объем.

4. Остаток раствора может быть удален вместе с наконечником при его сбросе или слит обратно в резервуар путем нажатия до второй остановки.

МЕТОД ПОВТОРОВ (рис. 7)

Данный метод представляет собой простой и быстрый способ для повторного дозирования одного и того же раствора. Наполните чистую ванночку для реагента раствором для раскапывания.

Рис. 7

1. Нажмите кнопку до второй остановки.

2. Погрузите наконечник примерно на 1 см в глубину раствора и плавно отпустите кнопку. Наконечник заполняется. Снимите излишки раствора о край резервуара.

3. Дозируйте раствор, плавно нажимая на кнопку до первой остановки. Удерживайте кнопку на первой остановке. Немного раствора останется в наконечнике. Этот остаток раствора не должен включаться в дозируемый объем.

4. Продолжайте дозирование, выполняя пункты 2 и 3.

ДОЗИРОВАНИЕ ЦЕЛЬНОЙ КРОВИ (рис. 8)

Для заполнения наконечника кровью выполните пункты 1 и 2 прямого метода работы. Тщательно вытрите наконечник сухой чистой тканью.

Рис. 8

1. Погрузите наконечник в реагент и нажмите кнопку до первой остановки. Убедитесь, что наконечник погружен в раствор.

2. Плавно отпустите кнопку в исходное положение. Наконечник будет заполняться раствором. Удерживайте наконечник в растворе.

3. Нажмите кнопку до первой остановки и плавно освободите. Повторяйте эту процедуру до тех пор, пока внутренняя поверхность наконечника не станет чистой.

4. В конце операции нажмите кнопку до второй остановки, чтобы полностью опустошить наконечник.

ТЕХНИЧЕСКОЕ ОБСЛУЖИВАНИЕ

Если дозатор Ленпипет Лайт не используется, убедитесь, что он хранится в вертикальном положении. Для этого мы рекомендуем настольный штатив для дозаторов .

ЕЖЕДНЕВНАЯ ПРОВЕРКА

Перед началом работы убедитесь, что на поверхности дозатора отсутствует грязь или пыль.

Особое внимание следует обратить на посадочный конус для наконечника. Нельзя использовать для очистки поверхности дозатора растворители за исключением 70% этанола.

ПЕРИОДИЧЕСКОЕ ОБСЛУЖИВАНИЕ

В случае, если дозатор используется каждый день, он должен подвергаться периодическому обслуживанию не менее 2-х раз в год.

РАЗБОРКА ДОЗАТОРОВ ДИАПАЗОНОМ ДО 1000 мкл

1. Отожмите вниз удалитель наконечника (рис. 9)

2. Открутите удалитель по направлению против часовой стрелки и вытяните его

3. Открутите конус наконечника по направлению против часовой стрелки с помощью ключа (рис. 10)

4. Вытяните поршень в сборе с другими частями. Некоторые части могут остаться в конусе наконечника – переверните его, чтобы вынуть все оставшиеся части.

5. Очистите поршень, пружину поршня и прокладочное кольцо сухой неворсистой тканью.

6. Проверьте конус наконечника на наличие посторонних частиц

7. Смажьте очищенные части смазкой, входящей в комплект поставки

8. Соберите дозатор обратно

Рис. 9


1-200 мкл **100-1000 мкл**

Рис. 10

КАЛИБРОВКА

Все дозаторы калибруются на фирме-изготовителе при температуре +22°C, используя дистиллированную воду. Обычно не требуется выполнять перекалибровку дозатора, однако рекомендуется заново калибровать дозатор для работы с вязкими жидкостями или с растворами другой температуры.

НЕОБХОДИМОЕ ОБОРУДОВАНИЕ И УСЛОВИЯ ДЛЯ ВЫПОЛНЕНИЯ ПРОВЕРКИ КАЛИБРОВКИ

Аналитические весы. Обратите внимание, чтобы цена деления аналитических весов была выбрана в соответствии с выбранным объемом калибруемого дозатора.

Объем	Цена деления
до 10 мкл	0,001 мг
10-100 мкл	0,01 мг
больше 100 мкл	0,1 мг

Жидкость для калибровки: дистиллированная вода.

Калибровка должна выполняться в помещении, где отсутствуют сквозняки, при постоянной (±0,5°C) температуре воды, дозатора и воздуха в диапазоне от 20°C до 25°C.
Относительная влажность должна быть выше 55%. Особенно важно поддерживать повышенную влажность воздуха при калибровке объемов менее 50 мкл, чтобы уменьшить потери жидкости при испарении.

ПРОВЕРКА КАЛИБРОВКИ

Наденьте плотно наконечник на дозатор. Наконечник, используемый первый раз, должен быть предварительно смочен путем забора и слива жидкости 3-5 раз. Затем выполните 10 дозирований. Пересчитайте полученный вес дозы в объем по специальной формуле.
Нельзя использовать измеренные значения с помощью весов без пересчета по формуле для дальнейших расчетов. Калибровка дозатора считается правильной, если вычисленные результаты укладываются в пределы, указанные в таблице. Если результаты не укладываются в границы, дозатор должен быть отрегулирован и проверен заново.

Объем	Точность %	Воспроизводимость %
1 мкл	± 8,0	7,0
5 мкл	± 5,0	5,0
10 мкл	± 2,5	3,0
20 мкл	± 2,0	3,0
25 мкл	± 2,0	3,0
50 мкл	± 2,0	2,5
100 мкл	± 1,5	2,0
200 мкл	± 1,5	2,0
250 мкл	± 1,5	2,0
500 мкл	± 1,0	1,0
1000 мкл	± 1,0	1,0

ФОРМУЛЫ ДЛЯ ВЫЧИСЛЕНИЯ РЕЗУЛЬТАТОВ

Точность (систематическая ошибка)
Точность - величина, характеризующая разницу между дозируемым объемом и установленным объемом на дозаторе.

$$\delta = \frac{V_{ср.} - V_{ном.}}{V_{ном.}} * 100\,\% \; ; \qquad V_{ср.} = \frac{\sum_{i=1}^{n} V_i}{n} = \frac{\sum_{i=1}^{n} M_i}{n\rho}$$

Где δ - точность (%); $V_{ср.}$ - среднее значение объема (мкл); $V_{ном.}$ - номинальный объем; V_i - объем дозы (мкл), M_i - вес дозы (мг); ρ - удельная плотность воды, 0,998 мг/мкл при +20-25°C; n - число измерений, 10.

Воспроизводимость (случайная, несистематическая ошибка)

Воспроизводимость - величина, характеризующая повторяемость дозирования.

$$\sigma = \frac{\sqrt{\frac{\sum_{i=1}^{n}(V_i - V_{ср.})^2}{n-1}}}{V_{ср.}} * 100\,\%$$

Где σ-воспроизводимость (%); $V_{ср.}$-среднее значение объема (мкл); V_i-объем дозы (мкл), n-число измерений, 10.

РЕГУЛИРОВКА

Рис. 12

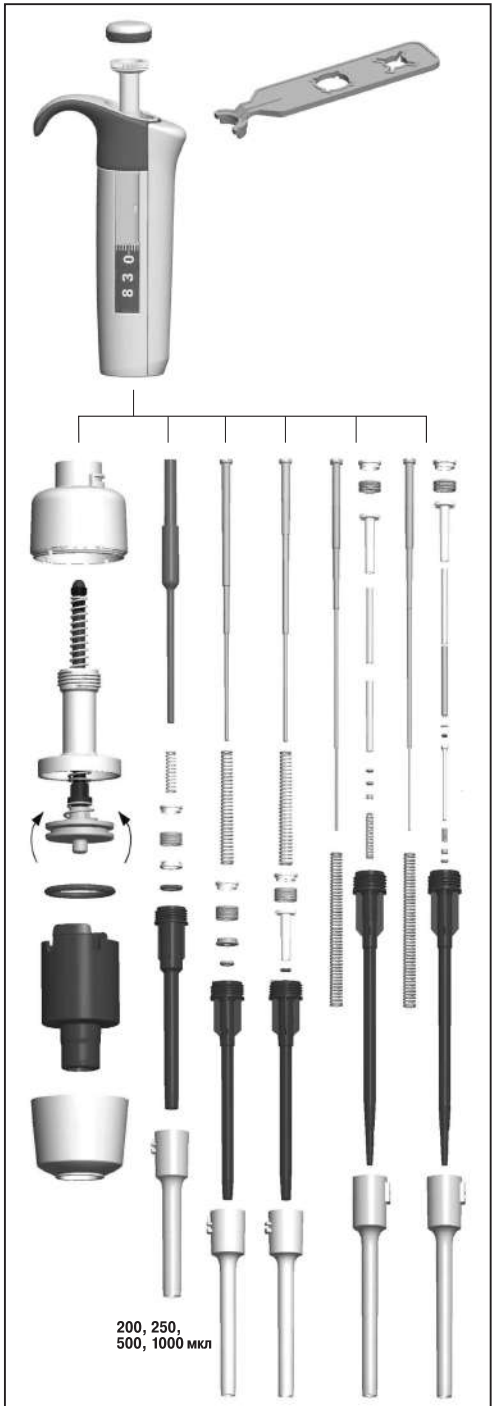
Регулировка выполняется с помощью специального ключа, поставляемого вместе с дозатором.
1. Поместите ключ на калибровочное кольцо, расположенное под операционной кнопкой.
2. Поверните ключ по часовой стрелке для увеличения дозируемого объема и в противоположном направлении для уменьшения объема.
3. После регулировки проверьте калибровку дозатора согласно приведенной выше инструкции.

УСТРАНЕНИЕ НЕИСПРАВНОСТЕЙ

Неполадка	Причина	Рекомендация
Утечка	Наконечник неплотно надет	Плотно наденьте наконечник
	Пыль или посторонние частицы между наконечником и конусом	Очистите конус и наденьте новый наконечник
	Пыль или посторонние частицы между плунжером, прокладкой и цилиндром	Очистите и смажьте плунжер, прокладку и цилиндр
	Цилиндр и прокладка плохо смазаны	Смажьте (см. инструкцию)
	Повреждено соединительное кольцо	Замените кольцо
Неточное дозирование	Неправильная работа дозатором	Внимательно следуйте инструкции
	Неправильно надет наконечник	Плотно наденьте наконечник
	Нарушение калибровки, например, из-за небрежного отношения с дозатором	Повторите калибровку в соответствии с инструкцией
Неточное дозирование с	Неподходящая калибровка. Работа с вязкими жидкостями требует перекалибровки	Перекалибруйте под используемую жидкость

СЕРВИСНОЕ ОБСЛУЖИВАНИЕ

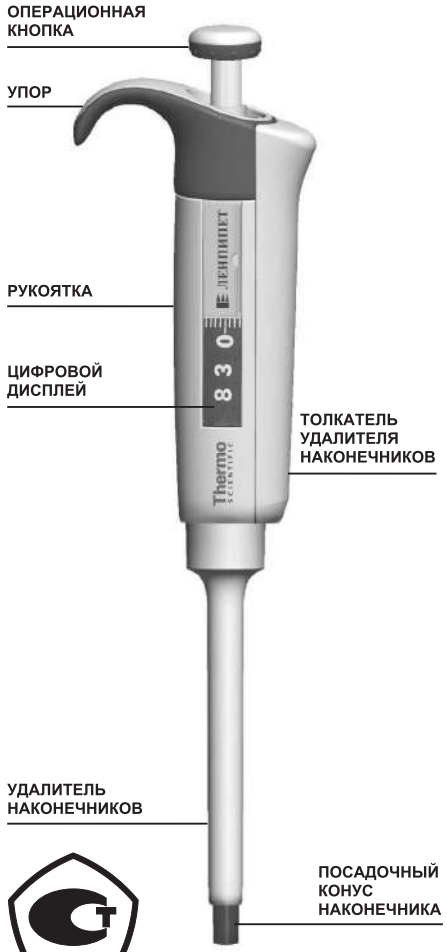
Дозатор Ленпипет Лайт сконструирован таким образом, чтобы он был легок в обслуживании в лаборатории. Однако, если Вы желаете произвести сервисное обслуживание Вашего дозатора у нас или нашего дилера, пожалуйста, убедитесь, что дозатор был продезинфицирован перед отправкой к нам. Пожалуйста, помните, что почтовая связь имеет право изымать посылки, содержащие инфекционный материал, а также что дезинфекция дозатора в сервисном центре увеличивает стоимость сервисного обслуживания или ремонта.



ЗАПАСНЫЕ ЧАСТИ

ОДНОКАНАЛЬНЫЙ ДОЗАТОР ФИКСИРОВАННОГО ОБЪЕМА ЛАЙТ

РУКОВОДСТВО ПО ЭКСПЛУАТАЦИИ



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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

FEDERAL SERVICE OF HEALTH CARE AND SOCIAL DEVELOPMENT CONTROL

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

REGISTRATION CERTIFICATE

№ ФСЗ 2011/10929

от **26 октября 2011 года** Срок действия: **не ограничен.**

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и подтверждает, что изделие медицинского назначения
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разрешено к импорту, продаже и применению на территории Российской Федерации

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения
и социального развития **Е.А. Тельнова**

014266

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ
FEDERAL SERVICE OF HEALTH CARE AND SOCIAL DEVELOPMENT CONTROL

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ

ATTACHMENT
№ ФСЗ 2011/10929

1. Наконечники полимерные одноразовые Finntip: 0,2-10 мкл; 0,2-20 мкл; 0,2-50 мкл; 0,3-30 мкл; 5-200 мкл; 0,5-250 мкл; 5-300 мкл; 1-100 мкл; 1-200 мкл; 5-100 мкл; 100-1000 мкл; 1000-5000 мкл; 2000-10000 мкл; 50-1500 мкл; 0,5-25 мкл; 20-200 мкл; 10-250 мкл; 0,5 мл; 1,25 мл; 2,5мл; 5 мл; 12,5 мл; 25 мл; 50 мл; 0,5-10 мкл; 0,5-100 мкл; 0,5-200 мкл; 150-1500 мкл; 0,5-30 мкл; 5-30 мкл; 50-1200 мкл.
2. Наконечники полимерные одноразовые Labtip Yellow (желтые).
3. Наконечники полимерные одноразовые Labtip Blue (синие).

Врио руководителя Федеральной службы по надзору в сфере здравоохранения и социального развития — **Е.А. Тельнова**

26 октября 2011 года

018788

ОПИСАНИЕ ДОЗАТОРА

Дозатор пипеточный Ленпипет Блэк представляет собой автоклавируемый дозатор для забора и дозирования точных объемов жидкости. Он работает по принципу воздушного вытеснения (т. е. между плунжером и жидкостью имеется объем воздуха) в одноразовом сменном наконечнике.

Одинадцать различных моделей одноканальных дозаторов переменного объема Ленпипет Блэк перекрывают диапазон дозирования от 0,5 мкл до 10 мл.

Кат.	Диапазон	Наконечник
4642022	0,5-5 мкл	10
4642032	1-10 мкл	10
4642042	1-10 мкл	250 Унив., 200 Удл., 300
4642052	2-20 мкл	50
4642062	2-20 мкл	250 Унив., 200 Удл., 300
4642132	5-50 мкл	250 Унив., 200 Удл., 300
4642072	10-100 мл	250 Унив., 200 Удл., 300
4642082	20-200 мкл	250 Унив., 200 Удл., 300
4642092	100-1000 мкл	1000
4642102	0,5-5 мл	5 мл
4642112	1-10 мл	10 мл

ЦИФРОВАЯ ИНДИКАЦИЯ

Установленный объем дозирования отображается на цифровом дисплее на рукоятке дозатора (рис.1).

Рис. 1

КОНСТРУКТИВНЫЕ МАТЕРИАЛЫ

Дозаторы Ленпипет Блэк изготавливаются из материалов высокой механической и химической стойкости.

НАКОНЕЧНИКИ

Для работы дозаторов Ленпипет Блэк рекомендуется использовать наконечники Ленпипет и Finntip. Они изготовлены из чистого обесцвеченного полипропилена, который считается материалом свободным от контаминации и прекрасно подходит для изготовления наконечников.

Кат. №№	Объем	Количество
9400310	0.2-10 мкл	1000 шт./уп
9400360	0.2-50 мкл	1000 шт./уп.
9401262	0.5-250 мкл	96 шт./штатив
9400267	0.5-250 мкл	20*96 шт. в башне
9400302	0.5-250 мкл	1000 шт./уп.
9400242	0.5-250 мкл	20000 шт./кор.
9401260	5-300 мкл	1000 шт./уп
9401282	100-1000 мкл	96 шт./штатив
9401032	100-1000 мкл	1000 шт./уп.
9401022	100-1000 мкл	5000 шт./кор.
9402052	1-5 мл	100 шт./уп.
9402150	1-10 мл	40 шт./уп.

ЭКСПЛУАТАЦИЯ ПИПЕТКИ

УСТАНОВКА ОБЪЕМА ДОЗИРОВАНИЯ

1. Требуемый объем устанавливается вращением операционной кнопки, расположенной наверху дозатора (рис. 2). Чтобы увеличить объем дозирования, поверните операционную кнопку против часовой стрелки, чтобы уменьшить объем - по часовой стрелке.

2. Убедитесь, что цифры, показывающие объем дозирования, целиком видны в окне дисплея и установлены до щелчка.

Рис. 2

3. Запрещается устанавливать объем, выходящий за границы диапазона дозирования.

Прилагая чрезмерное усилие при выкручивании операционной кнопки за пределы диапазона дозирования, Вы можете замять детали внутреннего механизма, что приведет к поломке дозатора и снятию изделия с гарантии.

Рис. 3

ЯРЛЫК БЕЗОПАСНОСТИ

На место ярлыка безопасности можно нанести необходимую Вам информацию, например, фамилию или дату последней поверки дозатора (рис.3)

СБРОС НАКОНЕЧНИКА

Чтобы исключить риск контаминации, каждый дозатор Ленпипет Блэк имеет специальный механизм для сброса наконечника. Чтобы сбросить наконечник, направьте дозатор на резервуар для отходов и нажмите на удалитель наконечника большим пальцем (рис. 4).

Рис. 4

ТЕХНИКА ДОЗИРОВАНИЯ

Всегда нажимайте и отпускайте операционную кнопку плавно, особенно при работе с растворами высокой вязкости. Никогда не отпускайте кнопку резко при обратном движении.

Убедитесь, что наконечник плотно держится на посадочном месте. Проверьте, нет ли на наконечнике посторонних частиц. Перед началом работы наполните и опустошите наконечник 2-3 раза раствором, с которым Вы собираетесь работать. Удерживайте дозатор в строго вертикальном положении при наборе реагента. Упор на дозаторе должен опираться на указательный палец. Убедитесь, что температура дозатора, наконечников и раствора одинакова.

ПРЯМОЙ МЕТОД (рис. 5)

Наполните чистую ванночку для реагента раствором для раскапывания.

Рис. 5

1. Нажмите на операционную кнопку до первой остановки.

2. Погрузите наконечник в раствор примерно на глубину 1 см и плавно отпустите кнопку. Извлеките наконечник, аккуратно снимая излишки раствора о край резервуара.

3. Дозируйте взятый раствор, плавно нажимая на кнопку до первой остановки. После примерно секундной паузы нажмите операционную кнопку до второй остановки. После выполнения данной операции наконечник должен полностью опустошиться.

4. Отпустите кнопку в исходное положение. Если необходимо, смените наконечник и продолжайте пипетирование.

ОБРАТНЫЙ МЕТОД (рис. 6)

Обратный метод используется для работы с жидкостями, имеющими высокую вязкость или склонность к вспениванию, а также данная техника рекомендуется для раскапывания очень малых объемов. Наполните чистую

Рис. 6

1. Держа дозатор вертикально, нажмите операционную кнопку до второй остановки.

2. Погрузите наконечник примерно на 1 см в глубину раствора и плавно отпустите кнопку. Наконечник наполняется. Извлекая наконечник, аккуратно снимите излишки раствора о край резервуара.

3. Дозируйте раствор, нажимая на кнопку до первой остановки. Удерживайте кнопку на первой остановке. Немного раствора останется в наконечнике. Этот остаток раствора не должен включаться в дозируемый объем.

4. Остаток раствора может быть удален вместе с наконечником при его сбросе или слит обратно в резервуар путем нажатия до второй остановки.

МЕТОД ПОВТОРОВ (рис. 7)

Данный метод представляет собой простой и быстрый способ для повторного дозирования одного и того же раствора. Наполните чистую ванночку для реагента раствором для раскапывания.

Рис. 7

1. Нажмите кнопку до второй остановки.

2. Погрузите наконечник примерно на 1 см в глубину раствора и плавно отпустите кнопку. Наконечник заполняется. Снимите излишки раствора о край резервуара.

3. Дозируйте раствор, плавно нажимая на кнопку до первой остановки. Удерживайте кнопку на первой остановке. Немного раствора останется в наконечнике. Этот остаток раствора не должен включаться в дозируемый объем.

4. Продолжайте дозирование, выполняя пункты 2 и 3.

ДОЗИРОВАНИЕ ЦЕЛЬНОЙ КРОВИ (рис. 8)

Для заполнения наконечника кровью выполните пункты 1 и 2 прямого метода работы. Тщательно вытрите наконечник сухой чистой тканью.

Рис. 8

1. Погрузите наконечник в реагент и нажмите кнопку до первой остановки. Убедитесь, что наконечник погружен в раствор.

2. Плавно отпустите кнопку в исходное положение. Наконечник будет заполняться раствором. Удерживайте наконечник в растворе.

3. Нажмите кнопку до первой остановки и плавно освободите. Повторяйте эту процедуру до тех пор, пока внутренняя поверхность наконечника не станет чистой.

4. В конце операции нажмите кнопку до второй остановки, чтобы полностью опустошить наконечник.

ТЕХНИЧЕСКОЕ ОБСЛУЖИВАНИЕ

Если дозатор Ленпипет Блэк не используется, убедитесь, что он хранится в вертикальном положении. Для этого мы рекомендуем настольный штатив для дозаторов .

ЕЖЕДНЕВНАЯ ПРОВЕРКА

Перед началом работы убедитесь, что на поверхности дозатора отсутствует грязь или пыль.

Особое внимание следует обратить на посадочный конус для наконечника. Нельзя использовать для очистки поверхности дозатора растворители за исключением 70% этанола.

ПЕРИОДИЧЕСКОЕ ОБСЛУЖИВАНИЕ

В случае, если дозатор используется каждый день, он должен подвергаться периодическому обслуживанию не менее 2-х раз в год.

РАЗБОРКА ДОЗАТОРОВ ДИАПАЗОНОМ ДО 1000 мкл

1. Отожмите вниз удалитель наконечника (рис. 9)

2. Открутите удалитель по направлению против часовой стрелки и вытяните его

3. Открутите конус наконечника по направлению против часовой стрелки с помощью ключа (рис. 10)

4. Вытяните поршень в сборе с другими частями. Некоторые части могут остаться в конусе наконечника – переверните его, чтобы вынуть все оставшиеся части.

Рис. 9

5. Очистите поршень, пружину поршня и прокладочное кольцо сухой неворсистой тканью.

6. Проверьте конус наконечника на наличие посторонних частиц

7. Смажьте очищенные части смазкой, входящей в комплект поставки

8. Соберите дозатор обратно

РАЗБОРКА ДОЗАТОРОВ ДИАПАЗОНОМ 1-10 мл

1. Отожмите вниз удалитель наконечника (рис.11)

2. Открутите удалитель по направлению против часовой стрелки

3. Отделите нижнюю часть удалителя (защелкивающее устройство)

4. Поверните внутренний цилиндр (черного цвета) по направлению против часовой стрелки и вытяните конус наконечника

5. Вытяните цилиндр, нажав на защелки на самом цилиндре

6. Очистите прокладочное кольцо и цилиндр

7. Соберите дозатор обратно

Рис. 10

Рис. 11

СТЕРИЛИЗАЦИЯ

Весь дозатор целиком может быть подвергнут стерилизации путем автоклавирования при 121°C (минимум 20 мин). Для этого не требуется специальных приготовлений. Вы можете использовать специальные приспособления для стерилизации, если Вам это необходимо.

После автоклавирования дозатор должен быть охлажден до комнатной температуры, по крайней мере, в течение двух часов. Перед началом пипетирования убедитесь в том, дозатор является сухим. Мы рекомендуем, чтобы Вы проверяли калибровку дозаторов 0,5-1000 мкл через каждые 25 циклов стерилизации и дозаторов 1-10 мл - через 10 циклов стерилизации.

КАЛИБРОВКА

Все дозаторы калибруются на фирме-изготовителе при температуре +22°С, используя дистиллированную воду. Обычно не требуется выполнять перекалибровку дозатора, однако рекомендуется заново калибровать дозатор для работы с вязкими жидкостями или с растворами другой температуры.

НЕОБХОДИМОЕ ОБОРУДОВАНИЕ И УСЛОВИЯ ДЛЯ ВЫПОЛНЕНИЯ ПРОВЕРКИ КАЛИБРОВКИ

Аналитические весы. Обратите внимание, чтобы цена деления аналитических весов была выбрана в соответствии с выбранным объемом калибруемого дозатора.

Объем	Цена деления
до 10 мкл	0,001 мг
10-100 мкл	0,01 мг
больше 100 мкл	0,1 мг

Жидкость для калибровки: дистиллированная вода.
Калибровка должна выполняться в помещении, где отсутствуют сквозняки, при постоянной (±0,5°С) температуре воды, дозатора и воздуха в диапазоне от 20°С до 25°С.
Относительная влажность должна быть выше 55%. Особенно важно поддерживать повышенную влажность воздуха при калибровке объемов менее 50 мкл, чтобы уменьшить потери жидкости при испарении.

ПРОВЕРКА КАЛИБРОВКИ

Дозаторы проверяются на максимальном и минимальном объемах. Например, дозатор Ленпипет Лайт 1-10 мкл тестируется на объемах 1 мкл и 10 мкл. Наконечник, используемый первый раз, должен быть предварительно смочен путем забора и слива жидкости 3-5 раз. Затем выполните дозирование 10 раз обоих объемов. Пересчитайте полученный вес дозы в объем по специальной формуле. Нельзя использовать измеренные значения с помощью весов без пересчета по формуле для дальнейших расчетов. Калибровка дозатора считается правильной, если вычисленные результаты укладываются в пределы, указанные в таблице. Если результаты не укладываются в границы, дозатор должен быть отрегулирован и проверен заново.

Диапазон	Объем мкл	Точность %	Воспр-сть %
0,5-5 мкл	5	± 5,0	5,0
	0,5	± 8,0	7,0
1-10 мкл	10	± 2,5	3,0
	1	± 8,0	7,0
2-20 мкл	20	± 2,0	3,0
	2	± 8,0	6,0
5-50 мкл	50	± 2,0	2,5
	5	± 5,0	5,0
10-100 мкл	100	± 1,5	2,0
	10	± 2,5	3,0
20-200 мкл	200	± 1,5	2,0
	20	± 2,0	3,0
100-1000 мкл	1000	± 1,0	1,0
	100	± 1,5	2,0
0,5-5 мл	5000	± 1,0	1,0
	500	± 1,0	1,0
1-10 мл	10000	± 1,0	1,0
	1000	± 1,0	1,0

ФОРМУЛЫ ДЛЯ ВЫЧИСЛЕНИЯ РЕЗУЛЬТАТОВ

Точность (систематическая ошибка)
Точность - величина, характеризующая разницу между дозируемым объемом и установленным объемом на дозаторе.

$$\delta = \frac{V_{ср.} - V_{ном.}}{V_{ном.}} * 100\% ; \qquad V_{ср.} = \frac{\sum_{i=1}^{n} V_i}{n} = \frac{\sum_{i=1}^{n} M_i}{n\rho}$$

Где δ - точность (%); $V_{ср.}$ - среднее значение объема (мкл); $V_{ном.}$ - номинальный объем; V_i - объем дозы (мкл), M_i - вес дозы (мг); ρ - удельная плотность воды, 0,998 мг/мкл при +20-25°С; n - число измерений, 10.

Воспроизводимость (случайная, несистематическая ошибка)

Воспроизводимость - величина, характеризующая повторяемость дозирования.

$$\sigma = \frac{\sqrt{\sum_{i=1}^{n} (V_i - V_{ср.})^2}}{\frac{n-1}{V_{ср.}}} * 100\%$$

Где σ-воспроизводимость (%); $V_{ср.}$-среднее значение объема (мкл); V_i-объем дозы (мкл), n-число измерений, 10.

РЕГУЛИРОВКА

Регулировка выполняется с помощью специального ключа, поставляемого вместе с дозатором.
1. Поместите ключ на калибровочное кольцо, расположенное под операционной кнопкой.
2. Поверните ключ по часовой стрелке для увеличения дозируемого объема и в противо-положном направлении для уменьшения объема.
3. После регулировки проверьте калибровку дозатора согласно приведенной выше инструкции.

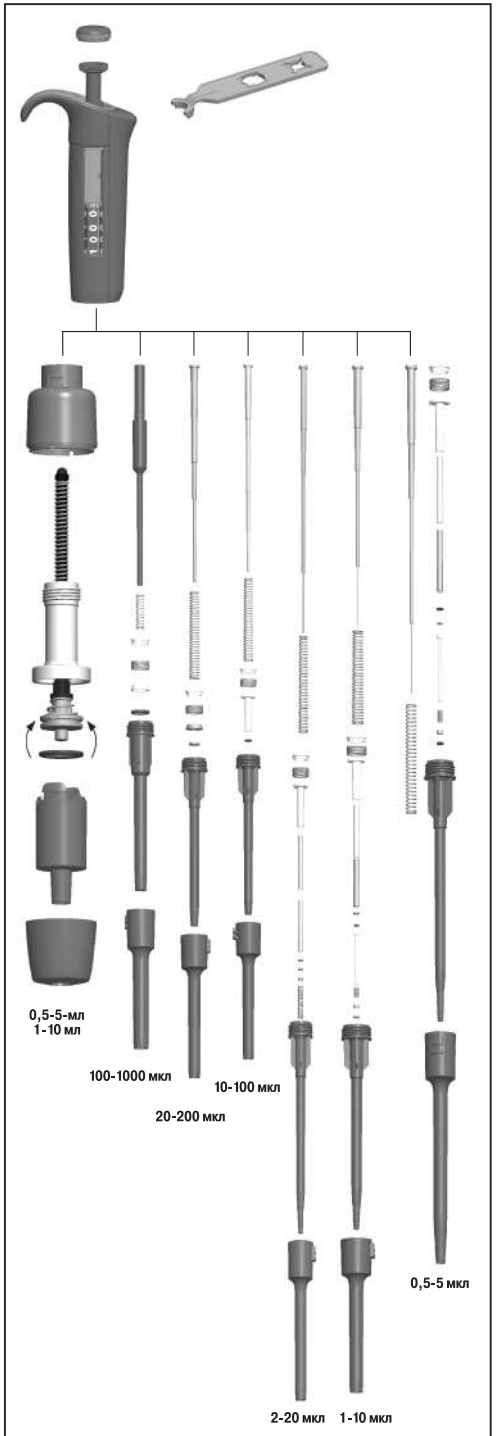
Рис. 12

УСТРАНЕНИЕ НЕИСПРАВНОСТЕЙ

Неполадка	Причина	Рекомендация
Утечка	Наконечник неплотно надет	Плотно наденьте наконечник
	Пыль или посторонние частицы между наконечником и конусом	Очистите конус и наденьте новый наконечник
	Пыль или посторонние частицы между плунжером, прокладкой и цилиндром	Очистите и смажьте плунжер, прокладку и цилиндр
	Цилиндр и прокладка плохо смазаны	Смажьте (см. инструкцию)
	Повреждено соединительное кольцо	Замените кольцо
Неточное дозирование	Неправильная работа дозатором	Внимательно следуйте инструкции
	Неправильно надет наконечник	Плотно наденьте наконечник
	Нарушение калибровки, например, из-за небрежного отношения с дозатором	Повторите калибровку в соответствии с инструкцией
Неточное дозирование с некот. жидкостями	Неподходящая калибровка. Работа с вязкими жидкостями требует перекалибровки	Перекалибруйте под используемую жидкость

СЕРВИСНОЕ ОБСЛУЖИВАНИЕ

Дозатор Ленпипет Блэк сконструирован таким образом, чтобы он был легок в обслуживании в лаборатории. Однако, если Вы желаете произвести сервисное обслуживание Вашего дозатора у нас или нашего дилера, пожалуйста, убедитесь, что дозатор был продезинфицирован перед отправкой к нам. Пожалуйста, помните, что почтовая связь имеет право изымать посылки, содержащие инфекционный материал, а также что дезинфекция дозатора в сервисном центре увеличивает стоимость сервисного обслуживания или ремонта.



ЗАПАСНЫЕ ЧАСТИ

ОДНОКАНАЛЬНЫЙ ДОЗАТОР ПЕРЕМЕННОГО ОБЪЕМА БЛЭК

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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 02 июня 2016 года № РЗН 2016/4183

На медицинское изделие
Планшет для определения групп крови П-50 по ТУ 9464-020-29508133-2016

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед" (ООО "МиниМед"), Россия, 241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
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Место производства медицинского изделия
242600, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 1

Номер регистрационного досье **№ РД-9867/66906 от 13.01.2016**

Вид медицинского изделия **327110**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции для медицинского изделия **94 6465**

приказом Росздравнадзора от 02 июня 2016 года № 4857
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения **М.А. Мурашко**

0019267

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
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№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

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НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа по сертификации: (подпись) **В. И. Погодин**

Председатель экспертной комиссии: (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Код ОКП 946465 Регистрационное удостоверение № РЗН 2016/4183 от 02.06.2016 г.

Паспорт

Планшет для определения групп крови П-50
ТУ 9464-020-29508133-2016

1. Назначение

Предназначен для определения групп крови методом прямой реакции агглютинации и проведения проб на совместимость донора и реципиента.

2. Основные технические характеристики

1. Габаритный размер, мм – (290±0,5) × (190±0,5) × (3,5±0,5).
2. Изготовлен из ударопрочного полистирола марки УПМ-0508. Не автоклавируется.
3. Конфигурация изделия – 10 строк по 5 лунок в каждой (50 лунок). Размер лунки, мм – (20±1,0) × (14±1,0) × (1,5±0,5). Каждая лунка имеет бортики, препятствующие растеканию реагентов.
4. Лунки маркированы на полях цифровой маркировкой (по длинной стороне отлиты цифры от 1 до 10, по короткой – I (0), II (A), III (B), IV (AB)). Дополнительный ряд лунок не маркирован и предназначен для дополнительного анализа крови донора и реципиента на совместимость.
5. Масса изделия, г - не более 80.
6. Устойчив к дезинфекции 3% раствором перекиси водорода по ГОСТ 177-88, предстерилизационной очистке ручным способом и стерилизации химическим методом по МУ 287-113.

3. Упаковывание, транспортирование и хранение

Индивидуально упакован. Упаковка обеспечивает сохранность изделий при транспортировке. Условия транспортирования изделий – условия хранения 5 по ГОСТ 15150-69 в крытом транспорте любого вида. Условия хранения изделий – 2 по ГОСТ 15150-69. После транспортирования в условиях отрицательных температур изделия должны быть выдержаны при нормальных климатических условиях не менее 4 ч.

4. Требования безопасности

При эксплуатации необходимо соблюдать правила безопасности при работе с пластиковыми изделиями.

5. Сведения об утилизации

Изделие не представляет опасности для окружающей среды, жизни и здоровья людей после окончания срока службы. Порядок утилизации изделия определяется Потребителем.

6. Гарантии изготовителя

Изготовитель: ООО «МиниМед», 241520, РФ, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17А.

Адрес производства: 242600, Россия, Брянская область, г. Дятьково, ул. Ленина, д. 182, корпус 1.

Изготовитель гарантирует соответствие планшета П-50 требованиям ТУ 9464-020-29508133-2016 при соблюдении потребителем условий транспортирования, хранения и эксплуатации. Гарантийный срок эксплуатации – 12 месяцев со дня ввода в эксплуатацию.

Гарантийный срок хранения – 3 года.

7. Свидетельство о приемке

Изделие изготовлено в соответствии с действующей технической документацией и признано годным для эксплуатации.

Начальник ОТК **Грузинцев С.А.**

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione	Data di Prima Emissione ITALCERT	Data di Rinnovo	Data di Scadenza
First Issue Date	*First Issue Date ITALCERT*	*Renewal Date*	*Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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viale Sarca, 336 - IT 20126 MILANO MI
tel. +39 0266104876 - fax +39 0266101479
E- mail italcert@italcert.it

Notified Body n° 0426

CERTIFICATE N° 181-01-00-DM

(in compliance with Annex V of the Directive 93/42/EEC)

ITALCERT

certifies the

Production Quality Assurance System applied for the manufacture and final inspection of "Medical Devices" - MD - by the manufacturer

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 - 20900 MONZA (MB) - ITALIY

in the headquarters located in

Regione Monforte, 30
14053 CANELLI (AT) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex V

and authorizes the manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC the MD reported in Annex 1 of this Certificate

THE GENERAL MANAGER

dr. ing. Roberto Cusolito

First issue date	Renewal date	Expire Date
2011-11-30	2016-11-30	2021-11-29

This certificate must be published only in integral form and accompanied by its Annex 1.
This certificate is the English translation of the certificate n° 181-01-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

ITALCERT

ITALCERT S.r.l.
viale Sarca, 336 - IT 20126 MILANO MI
tel. +39 0266104876 - fax +39 0266101479
E- mail italcert@italcert.it
Notified Body n° 0426

Annex 1 to Certificate n° 181-01-00-DM

Surgically invasive medical devices intended for transient use (class IIa)

Swabs for the collection and the preservation of biological samples with or without transport medium, also for surgical application.

Milan, 2016-11-30

dr. ing. Roberto Cusolito
General Manager

IMPOSTA DI BOLLO ASSOLTA

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E
DEL SERVIZIO FARMACEUTICO
UFFICIO 04 ex DGFDM – DIAGNOSTICI IN VITRO

DGDMF/04/I.5.1.e.2/2016/217

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n .332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza datata 04/07/2016 presentata dalla ditta NUOVA APTACA SRL con sede legale in Via Monte Bianco, 4 -20900- Monza (MB), Italia, e sede operativa in Regione Monforte, 3 – 14053- Canelli (AT), Italia, C.F. 07520900155, P.IVA 00862050960;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 07 Agosto 2012;
VISTI gli atti d'ufficio;

HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical devices;*
HAVING REGARD *to legislative Decree (D.lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC Directive;*
HAVING REGARD *to the request dated 04/07/2016 submitted by the company* NUOVA APTACA SRL *with registered place of business in Via Monte Bianco, 4 – 20900- Monza (MB), Italy and operative site in Regione Monteforte, 3 – 14053- Canelli (AT), Italy,* C.F. 07520900155, P.IVA 00862050960*;*
WHEREAS *this company paid the fees required by Ministerial Decree (D.M.) August 07, 2012;*
HAVING REGARD to *the official deeds;*

SI ATTESTA

IT IS ATTESTED

che la ditta NUOVA APTACA SRL, sede legale in Via Monte Bianco, 4 – 20900- Monza (MB), Italia e sede operativa in Regione Monforte, 3 – 14053- Canelli (AT), Italia, C.F. 07520900155, P.IVA 00862050960, ha marcato CE, come dispositivi medico-diagnostici in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i seguenti prodotti:

that the Company NUOVA APTACA SRL *with registered place of business in Via Monte Bianco 4 – 20900- Monza (MB), Italy and operative site in Regione Monteforte, 3 – 14053- Canelli (AT), Italy,* C.F. 07520900155, P.IVA 00862050960, *affixed CE marking as in vitro diagnostic medical devices, according to the Directive 98/79/EC, to the following products:*

Cod. 0 18138 - 10 ml conical test tubes, PS, cap and label, sterile ind. Wrapped, case
Cod. 10001 - Macro tips Gilson type, vol. 2,000-10,000ul, neutral,
Cod. 10001/SG - Macro tips Gilson type, vol. 2,000-10,000ul, neutral,
Cod. 10005 - Macro tips Biohit type, vol. 2,000-10,000ul, neutral,
Cod. 10005/SG - Macro tips Biohit type, vol. 2,000-10,000ul, neutral,
Cod. 1001/B - Tips Beckman type in PP, vol. 101-1000 ul, neutral,
Cod. 1001/B/SG - Tips Beckman type in PP, vol. 101-1000 ul, neutral,
Cod. 1001/E - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 1001/E/200 - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 1001/E/500 - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 1001/E/CS - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour, confezione singola
Cod. 1001/E/SG - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 1001/E/SG/CS - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,

Cod. 1001/EN - Tips Eppendorf type in PP, vol. 100-1000ul, neutral,
Cod. 1001/G - Tips Gilson type in PP, vol. 100-1000 ul, blue colour,
Cod. 1001/G/250 - PIPETTE TIPS 101-1000 UL BLUE GILSON TYPE
Cod. 1001/G/CS - PIPETTE TIPS 101-1000 UL BLUE GILSON TYPE, confezione singola
Cod. 1001/G/SG - Tips Gilson type in PP, vol. 100-1000 ul, blue colour,
Cod. 1001/G/SG/CS - Tips Gilson type in PP, blue colour, 100-1000 ul, sterile ind. Wrapped
Cod. 1001/O - Tips Oxford type in PP, vol. 101-1000ul, green colour,
Cod. 1001/O/SG - Tips Oxford type in PP, vol. 101-1000ul, green colour,
Cod. 1001/OB - Tips Oxford type in PP, vol. 101-1000ul, blue colour,
Cod. 1001/OB/SG - Tips Oxford type in PP, vol. 101-1000ul, blue colour,
Cod. 1001/U - Universal tips in PP, vol. 100-1000 ul, blue colour,
Cod. 1001/U/SG - Universal tips in PP, vol. 100-1000 ul, blue colour,

Cod. 1001/UN - Universal tips in PP, vol. 50-1000 ul, neutral colour,
Cod. 1001/UN/SG - Universal tips 50-1000ul, graduated, sterile
Cod. 1002/U - Tips Eppendorf type in PP, 20-300ul graduated, neutral,
Cod. 1002/U/SG - Tips Eppendorf type in PP, 20-300ul graduated, neutral,
Cod. 1003 - 1.5ml micro test tubes in PP, Eppendorf type, with cap
Cod. 1003* - 1.5ml micro test tubes in PP, Eppendorf type, with cap,
Cod. 1003/B - 1.5ml micro test tubes in PP, Eppendorf type, without cap
Cod. 1003/C - 0.5ml micro test tubes in PE, Beckman type, with cap
Cod. 1003/F - 1.5ml micro test tubes in PP, Eppendorf type, graduated,
Cod. 1003/G - 1.5ml micro test tubes in PP, Eppendorf type, graduated,
Cod. 1003/G* - 1.5ml micro test tubes in PP, Eppendorf type, graduated,
Cod. 1003/G/500 - 1,5 micro test tube PP. eppendorf type.grad, bags 500
Cod. 1003/G/SG - 1.5ml micro test tubes in PP, Eppendorf type, graduated,
Cod. 1003/HT - 2ml micro test tubes in PP for Hyland-Travenol, without
Cod. 1003/HT/250 - 2ml micro test tubes in PP for Hyland-Travenol, without
Cod. 1003/SG - 1.5ml micro test tubes in PP, Eppendorf type, with cap,
Cod. 1003/SG/100 - MICRO T. TUBES EPPENDORF TYPE IN PP Ø10x40 MM VOL. 1.5 ML
Cod. 1003/SG/50 - MICRO T. TUBES EPPENDORF TYPE IN PP Ø10x40 MM VOL 1.5 ML
Cod. 1003/V - 0.5ml micro test tubes in PP, Vitraton Akes type, with cap
Cod. 1003/V* - 0.5ml micro test tubes in PP, Vitraton Akes type, with cap
Cod. 1005 - 10ml cylindrical test tubes in PS, without rim, graduated
Cod. 1005 - 10ml cylindrical test tubes in PS, without rim, graduated
Cod. 1005 - 10ml cylindrical test tubes in PS, without rim, graduated
Cod. 1005/S - 10ml cylindrical test tubes in PS, without rim, graduated
Cod. 1006 - 3ml cylindrical test tubes in PS, graduated, without rim,
Cod. 1006/MO - 3ml cylindrical test tubes in PP, graduated, without rim,
Cod. 10061 - TPX cylindrical test tubes, 7 ml, with rim, not graduated,
Cod. 10062 - TPX cylindrical test tubes, 10 ml, with rim, not graduated
Cod. 10063 - TPX cylindrical test tubes, 16 ml, with rim, not graduated
Cod. 10064 - TPX cylindrical test tubes, 26 ml, with rim, not graduated
Cod. 10065 - TPX cylindrical test tubes, 30 ml, with rim, not graduated
Cod. 10066 - TPX cylindrical test tubes, 31 ml, with rim, not graduated
Cod. 10067 - TPX cylindrical test tubes, 48 ml, with rim, not graduated
Cod. 10068 - TPX cylindrical test tubes, 75 ml, with rim, not graduated
Cod. 10069 - TPX cylindrical test tubes, 110ml, with rim, not graduated
Cod. 10070 - TPX cylindrical test tubes, 160ml, with rim, not graduated
Cod. 10071 - TPX cylindrical test tubes, 200ml, with rim, not graduated
Cod. 1008/C - Caps in PE Ø11 mm for test tubes for RIA art. 1014/C
Cod. 1009/C/E - 10ml conical test tubes in PS, with rim and label, graduated,
Cod. 1009/C/T - 10ml conical test tubes in PS, with rim and cap, graduated,
Cod. 1009/C/T/CS - 10ml conical test tubes in PS, with rim and with red cap,
Cod. 1009/C/T/SG - 10ml conical test tubes in PS, with rim and with red cap,
Cod. 1009/C/T/SG - 10ml conical test tubes in PS, with rim and with red cap,
Cod. 1009/C/T/SG/CS - 10ml conical test tubes in PS, cap, sterile ind. Wrapped
Cod. 1009/C/T/SGCS - 10ml conical test tubes in PS, cap, sterile ind. Wrapped
Cod. 1009/C/TB - 10ml conical test tubes in PS, with rim and with white cap
Cod. 1009/C/TB/E - 10ml conical test tubes in PS, with rim, white cap and label
Cod. 1009/C/TB/E/SG - 10ml conical test tubes in PS, with rim, white cap and label
Cod. 1009/C/TBE/CS - 10ml conical test tubes in PS, with rim, label and white cap,
Cod. 1009/C/TE - 10ml conical test tubes in PS, with rim, label and cap,
Cod. 1009/C/TE/2000 - 10ml conical test tubes in PS, cap and label, graduated
Cod. 1009/C/TE/CS - 10ml conical test tubes in PS, with rim, label and cap,
Cod. 1009/C/TE/SG - 10ml conical test tubes in PS, with rim, label and cap,
Cod. 1009/C/TE/SG/CS - 10ml conical test tubes in PS, with rim label cap, graduated
Cod. 1009/C/TG - 10ml conical test tubes in PS, with rim and with white cap
Cod. 1009/C/TGE/SG - 10ml conical test tubes in PS, with rim, label and yellowcap,
Cod. 1009/C/TR - 10ml conical test tubes in PS, with rim, graduated,
Cod. 1009/CTBESGCS - 10ml conical test tubes in PS, with rim, white cap and label
Cod. 1009/E - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1009/E/SG - 10ml cylindrical test tubes in PS, with rim, without cap,
Cod. 1009/MO/E - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1009/MO/T - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1009/MO/T/100 - 10ml cylindrical test tubes in PP, with cap
Cod. 1009/MO/T/AL - 10ml cylindrical test tubes in PP, cap with tongue
Cod. 1009/MO/T/CS - 10ml cylindrical test tubes in PP, graduated, with rim, red
Cod. 1009/MO/T/SG - 10ml cylindrycal test tubes in PP, Ø16x100mm, graduated, with
Cod. 1009/MO/TB - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1009/MO/TB/E - 10ml cylindrical test tubes in PP, with rim and white cap,
Cod. 1009/MO/TB/E/SG - 10ml cylindrical test tubes in PP, graduated, with rim, label
Cod. 1009/MO/TBL/E/SG - 10 ml cylindrical test tubes in PP, blue cap, label, sterile
Cod. 1009/MO/TE - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1009/MO/TE/SG - 10ml cylindrical test tubes in PP, graduated, with rim, label
Cod. 1009/MO/TE/SG/C - 10ml cylindrical test tubes in PP, cap and label, sterile ind wrapped
Cod. 1009/MO/TE/SG/CS - 10ml cylindrical test tubes in PP, cap and label, sterile ind wrapped

Cod. 1009/MO/TG - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1009/MO/TG/E/SG - 10ml cylind test tubes PP with rim & label, Ø16x100 graduated
Cod. 1009/MO/TGE2000 - 10ml cylindrical test tubes in PP, yellow cap and label
Cod. 1009/MO/TR - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1009/MO/TRE2000 - 10ml cylindrical test tubes in PP, red cap and label
Cod. 1009/MO/TV/E/SG - 10ml cylind test tubes PP with rim & label, Ø16x100 graduated
Cod. 1009/MOC/E - 10ml conical test tubes in PP, with rim and label, graduated,
Cod. 1009/MOC/T - 10ml conical test tubes in PP, with rim and cap, graduated,
Cod. 1009/MOC/T/SG - 10 ml conical test tubes in PP, cap, sterile
Cod. 1009/MOC/TB - 10ml conical test tubes in PP, with rim and white cap,
Cod. 1009/MOC/TE - 10ml conical test tubes in PP, with rim, label and cap,
Cod. 1009/MOC/TE/SG - 10ml conical test tubes in PP, with rim, label and cap,
Cod. 1009/MOC/TE/SG/CS - 10 ml conical test tubes in PP, cap and label, sterile ind. Wrapped
Cod. 1009/MOC/TR - 10ml conical test tubes in PP, with rim and inserted red cap,
Cod. 1009/MOC/TR/E - 10ml conical test tubes in PP, with rim, label and red cap,
Cod. 1009/MOCTESG - CONIC. 10 ML STER. TEST TUBES IN PP 16x100-W/CAP AND LABEL
Cod. 1009/MOCTESGCS - 10ml conical test tubes in PP, with rim label cap, graduated
Cod. 1009/MOCTSG - 10ml conical test tubes in PP, graduated, Ø16x100mm, red cap,
Cod. 1009/MOTBESGCS - 10ml cylind test tubes PP with rim & label, Ø16x100 graduated
Cod. 1009/MOTBL/E/SG - 10ml cylind test tubes PP with rim & label, Ø16x100 graduated
Cod. 1009/MOTESG100 - 10ml cylindrical test tubes in PP, cap and label, sterile
Cod. 1009/MOTESGCS - 10ml cylindrical test tubes in PP, graduated, with rim label
Cod. 1009/T - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1009/T/SG - 10ml cylindrical test tubes in PS, graduated, with rim and
Cod. 1009/T/SG/CS - 10ml cylindrical test tubes in PS, graduated with rim and cap
Cod. 1009/TA/E/SG/CS - 10ml cylindrical test tubes PS graduated,label and light blue
Cod. 1009/TB - 10ml cylindrical test tubes in PS, rim, graduated, Ø16x100 mm
Cod. 1009/TB/E - 10ml cylindrical test tubes in PS, rim, graduated, Ø16x100 mm
Cod. 1009/TB/E/RACK - 10ml cylindrical test tubes in PS, rim, graduated, Ø16x100mm
Cod. 1009/TB/E/SG/CS - 10ml cylindrical test tubes in PS, graduated, label and white
Cod. 1009/TE - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1009/TE/CS - 10ml cylindrical test tubes in PS, graduated, with rim label,
Cod. 1009/TE/SG - 10ml cylindrical test tubes in PS, graduated, with rim label
Cod. 1009/TE/SG/20 - CYLINDRICAL TEST TUBES 10ML PS 16X100 W/CAP AND LABEL STERILE
Cod. 1009/TE/SG/AL - 10ml cylindrical test tubes PS graduated, with rim label and
Cod. 1009/TE/SG/CS - 10ml cylindrical test tubes in PS, graduated, with rim label
Cod. 1009/TE/SG/EST - 10ml cylindr. test tubes in PS graduated, rim, sterile label,
Cod. 1009/TG/E/SG/CS - 10ml cylindrical test tubes in PS graduated, label and yellow
Cod. 1009/TR - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1009/TR/E - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1009MO/TR/ESGCS - 10ml cylindrical test tubes in PP, cap and label, sterile ind. Wrapped
Cod. 1009MOCTESGCS - 10ml conical test tubes in PP, cap and label, sterile ind. Wrapped
Cod. 1009MOTESG100 - 10ml cylindri. test tube in PP Ø16x100 graduated, rim and cap
Cod. 101 - Petri dishes Ø 90 mm, without triple vents, in PS
Cod. 101/5 - petri dishes 90mm w/out vents in PS 5 pcs/bag
Cod. 101/AN - Petri dishes Ø 90 mm, without triple vents, in PS
Cod. 101/B - Ø90 mm petri dishes in PS, without vents, aseptic
Cod. 101/CS - PETRI DISHES IN PS,DIAM.90MM- STERILIZED-IN
Cod. 101/SG - Petri dishes Ø 90 mm, without triple vents, in PS
Cod. 101/SG/AN - Petri dishes Ø 90 mm, without triple vents, in PS
Cod. 101/SG/B - Ø90 mm petri dishes in PS, without vents, sterile
Cod. 1010/E - 3ml cylindrical test tubes in PS, graduated, without rim,
Cod. 1010/MO/E - 3ml cylindrical test tubes in PP, graduated, without rim,
Cod. 1010/MO/T - 3ml cylindrical test tubes in PP, graduated, without rim,
Cod. 1010/MO/TE - 3ml cylindrical test tubes in PP, graduated, without rim,
Cod. 1010/MO/TE/SG - 3ml cylindrical test tubes in PP, graduated, with cap label,
Cod. 1010/SB - Tips Gilson diamond type, 2-200 ul
Cod. 1010/T - 3ml cylindrical test tubes in PS, graduated, without rim,
Cod. 1010/TE - 3ml cylindrical test tubes in PS, graduated, without rim,
Cod. 1010/TE/SG - 3ml cylindrical test tubes in PS, graduated, with cap label,
Cod. 1011 - 18ml faeces containers in PS, with pressure cap and spoon,
Cod. 1011/E - 18ml faeces containers in PS, with pressure cap and spoon,
Cod. 1011/E/50 - 18ml faeces containers in PS, with pressure cap and spoon,
Cod. 1011/E/AST - 18 ml faeces containers in PS, cap and spoon, label
Cod. 1011/E/SG - 18ml faeces containers in PS, with pressure cap and spoon,
Cod. 1011/E/SG/CS - 18 ml faeces containers in PS, cap and spoon, label, sterile ind wrapped
Cod. 1011/SG - 18ml faeces containers in PS, with pressure cap and spoon,

Cod. 1011/SG/CS - 18ml faeces containers in PS, with pressure cap and spoon,
Cod. 10110 - SEDI-RATE E.S.R. System Graduated pipette + test tube
Cod. 10110/16 - SEDI-RATE ESR System Graduated pipette + test tube
Cod. 10110/PR - TEST TUBE 0,2 NA CITRATE
Cod. 1012 - 18ml specimen containers, in PS, with pressure cap,
Cod. 1012/SG - 18ml specimen containers, in PS, with pressure cap,
Cod. 10121 - PP cylindrical test tubes, 7 ml, with rim, not graduated,
Cod. 10122 - PP cylindrical test tubes, 10 ml, with rim, not graduated
Cod. 10123 - PP cylindrical test tubes, 16 ml, with rim, not graduated
Cod. 10124 - PP cylindrical test tubes, 26 ml, with rim, not graduated
Cod. 10125 - PP cylindrical test tubes, 30 ml, with rim, not graduated
Cod. 10126 - PP cylindrical test tubes, 31 ml, with rim, not graduated
Cod. 10127 - PP cylindrical test tubes, 48 ml, with rim, not graduated
Cod. 10128 - PP cylindrical test tubes, 75 ml, with rim, not graduated
Cod. 10129 - PP cylindrical test tubes, 110ml, with rim, not graduated
Cod. 1013 - 18ml containers without cap, in PS, Ø22 x 63 mm
Cod. 10130 - PP cylindrical test tubes, 160ml, with rim, not graduated
Cod. 10131 - PP cylindrical test tubes, 200ml, with rim, not graduated
Cod. 1014 - 4ml cylindrical test tubes for RIA, in PS, graduated at 2ml,
Cod. 1014/C - 3ml cylindrical test tubes for RIA, in PS, graduated at 2ml,
Cod. 1014/C/T - 3ml cylindrical test tubes for RIA, in PS, graduated at 2ml, cap
Cod. 1014/C+1008/C - 3ml cylindrical test tubes for RIA + cap not assembled
Cod. 1014+1128 - 4ml cylindrical test tubes for RIA, PS, graduated, Ø12x70mm
Cod. 1015 - Cuvettes for spectrophotometer MACRO type, 2 - 4 ml, in PS,
Cod. 1015/K - Cuvettes for spectrophotometer MACRO type, PS, 2-4ml
Cod. 1015/SG - Cuvettes for spectrophotometer MACRO type 4.5 ml, PS, sterile
Cod. 10150 - 10ml test tubes with screw cap and self-standing base, in PP,
Cod. 10150/E - 10 ml skirted test tubes in PP, graduated, label
Cod. 10150/SG - 10ml test tubes with screw cap and self-standing base, in PP,
Cod. 10150/SG/CS - 10ml test tubes with screw cap and self-standing base, in PP,
Cod. 1016 - Cuvettes for spectrophotometer SEMI-MICRO type 0.5-2ml, in PS
Cod. 10160 - 5ml test tubes with screw cap and self-standing base, in PP,
Cod. 10160/E - 5 ml skirted test tubes in PP, graduated, label
Cod. 10160/SG - 5ml test tube in PP with screw cap and selfstanding base,
Cod. 10160/SG/CS - 5ml test tube in PP with screw cap and selfstanding base,
Cod. 1018 - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1018/MO - 5ml cylindrical test tubes in PP, with rim, graduated,
Cod. 10181 - PS cylindrical test tubes, 7 ml, with rim, not graduated,
Cod. 10182 - PS cylindrical test tubes, 10 ml, with rim, not graduated
Cod. 10183 - PS cylindrical test tubes, 16 ml, with rim, not graduated
Cod. 10184 - PS cylindrical test tubes, 26 ml, with rim, not graduated
Cod. 10185 - PS cylindrical test tubes, 30 ml, with rim, not graduated
Cod. 10186 - PS cylindrical test tubes, 31 ml, with rim, not graduated
Cod. 10187 - PS cylindrical test tubes, 48 ml, with rim, not graduated
Cod. 10188 - PS cylindrical test tubes, 75 ml, with rim, not graduated
Cod. 10189 - PS cylindrical test tubes, 110ml, with rim, not graduated
Cod. 10190 - PS cylindrical test tubes, 160ml, with rim, not graduated
Cod. 10191 - PS cylindrical test tubes, 200ml, with rim, not graduated
Cod. 10205 - 5ml cylindrycal test tubes in PP, with hinged-lid, Ø13x52mm,
Cod. 10206 - 10ml cylindrycal test tubes in PP, with hinged-lid, Ø16x80mm,
Cod. 1022 - Technicon sample cups 1.5 ml, in PS, Ø13.80 x 22.60 mm
Cod. 1022/5000 - Technicon sample cups 1.5 ml, in PS, Ø13.80 x 22.60 mm
Cod. 1022/V - Centrifichem sample cups 2 ml, in PS, Ø16 x 24 mm
Cod. 1023 - Technicon sample cups 4 ml, in PS, Ø17.26 x 37.90 mm
Cod. 1023/K/AN - Technicon sample cups 4 ml, in PS, Ø17.26 x 37.90 mm
Cod. 1024 - Gemsaec sample cups 0.5 ml, in PS, Ø13.55 x 24.50 mm
Cod. 1024/V - Centrifichem sample cup 0.25ml in PS, Ø14 x 16 mm
Cod. 10241 - TPX conical test tubes, 10 ml, with rim, not graduated
Cod. 10242 - TPX conical test tubes, 16 ml, with rim, not graduated
Cod. 1025 - 5ml flat bottom test tubes in PS, graduated, with rim,
Cod. 1025/B - 5ml flat bottom test tubes in PS, graduated, with rim,
Cod. 1025/MO - 5ml flat bottom test tubes in PP, graduated, with rim,
Cod. 1025/MO/B - 5ml flat bottom test tubes in PP, graduated, with rim,
Cod. 1025/U - Universal tips in PP, vol. 50-1,250 ul, graduated,
Cod. 1025/U/SG - Universal tips 50-1250ul, graduated, sterile
Cod. 10251 - 3ml test tubes in PE
Cod. 10252 - 5 ml test tubes in PE
Cod. 1027 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.01 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.01* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.02 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.02* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.03 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.03* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.04 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,

Cod. 1027.04* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.05 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.05* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.06 - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 1027.06* - Stoppers closed at the bottom in PE for test tubes Ø16 mm,
Cod. 10271 - PP conical test tubes, 10 ml, with rim, not graduated
Cod. 10272 - PP conical test tubes, 16 ml, with rim, not graduated
Cod. 1028 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.01 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.01* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.02 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.02* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.03 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.03* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.04 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.04* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.05 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.05* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.06 - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1028.06* - Stoppers closed at the bottom in PE for test tubes Ø12 mm,
Cod. 1029 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.01 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.01* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.02 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.02* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.03 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.03* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.04 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.04* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.05 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.05* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.06 - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1029.06* - Stoppers closed at the bottom in PE for test tubes Ø13 mm,
Cod. 1030 - 130ml urine containers in PS, with pressure cap, graduated,
Cod. 1030/E - 130ml urine containers in PS, with pressure cap, graduated,
Cod. 1030/E/CS - 130ml urine containers in PS, pressure cap, graduated, label
Cod. 1030/E/SG - 130ml urine containers in PS, pressure cap, graduated, label
Cod. 1030/E/TS - 130ml urine containers in PS, label
Cod. 1030/MO - 130ml urine containers in PP, with pressure cap, graduated,
Cod. 1030/MO/E - 130ml urine containers in PP, label
Cod. 1030/MO/E/SG - 130ml urine containers in PP, label, sterile
Cod. 1030/MO/SG - 130ml urine containers in PP, with pressure cap, graduated,
Cod. 1030/MO/T - 130ml urine containers in PP, with inserted pressure cap,
Cod. 1030/R - 130ml urine containers in PS, with pressure cap red colour
Cod. 1030/S - 130ml urine containers in PS, without cap, graduated,
Cod. 1030/SG - 130ml urine containers in PS, with pressure cap, graduated,
Cod. 1030/T - 130ml urine containers in PS, with inserted pressure cap,
Cod. 1030/TS - 130ml urine containers in PS, with inserted pressure cap, sterile
Cod. 1031 - 12ml urine test tubes wide mouth, in PS, with cap,
Cod. 1031/500+1017 - 12ml urine test tubes wide mouth, PS, with cap and label
Cod. 1031/CS - 12ml urine test tubes wide mouth, in PS, with cap,
Cod. 1031/CS/PI - 12ml urine test tubes in PS, graduated, Ø17x105mm, hygienic
Cod. 1031/E - 12ml urine test tubes wide mouth, in PS, with cap label,
Cod. 1031/E/500 - 12ml urine test tubes wide mouth, in PS, with cap label,
Cod. 1031/E/S - 12ml urine test tubes wide mouth, in PS, with cap label,
Cod. 1031/E/SG/CS - 12ml urine test tubes wide mouth, PS, cap and label, grad
Cod. 1031/E/SG/CS/PI - 12ml urine test tubes in PS, graduated, Ø17x105mm, sterile ind wrapped
Cod. 1031/G - 12ml urine test tubes wide mouth, in PS, with yellow cap,
Cod. 1031/S - 12ml urine test tubes wide mouth, in PS, without cap,
Cod. 1031/S/1500 - 12ml urine test tubes wide mouth PS, graduated, Ø17x105mm
Cod. 1031/SG/CS - 12ml urine test tubes wide mouth, in PS, with cap, grad.,
Cod. 1031/SG/CS/PI - 12ml urine test tubes, in PS, graduat. Ø17x105, cap hygienic
Cod. 1031/T - 12ml urine test tubes wide mouth, PS, with inserted cap,
Cod. 1031/TE - 12ml urine test tubes wide mouth, PS, with inserted cap,
Cod. 1031/TE/SG - 12ml urine test tubes wide mouth, PS, with inserted cap,
Cod. 1034 - Caps in PE for urine test tube wide mouth art. 1031/S
Cod. 1034.01 - Caps in PE for urine test tube wide mouth art. 1031/S
Cod. 1034.02 - Caps in PE for urine test tube wide mouth art. 1031/S
Cod. 1034/R - Caps in PE for urine test tube wide mouth art. 1031/S

Cod. 1035/E - 5ml flat bottom test tubes in PS, graduated, with rim and
Cod. 1035/MO/E - 5ml flat bottom test tubes in PP, graduated, with rim and
Cod. 1035/MO/T - 5ml flat bottom test tubes in PP, graduated, with rim and
Cod. 1035/MO/TE - 5ml flat bottom test tubes in PP, with rim, graduated,
Cod. 1035/MO/TE/SG - 5ml flat bottom test tubes in PP, with rim cap and label,
Cod. 1035/T - 5ml flat bottom test tubes in PS, graduated, with rim and
Cod. 1035/TE - 5ml flat bottom test tubes in PS, with rim, graduated,
Cod. 1035/TE/SG - 5ml flat bottom test tubes in PS, with rim cap and label,
Cod. 10351 - 50ml conical test tubes in PP, with light blue screw cap,
Cod. 10351/E - 50ml conical test tubes in PP, with screw cap, graduated,
Cod. 10351/E/SG - 50ml conical test tubes in PP, screw cap, graduated Ø30x115mm, label, sterile ind wrapped
Cod. 10351/P - 50 ml conical test tubes in PP, screw cap not assembled, Ø30x115mm
Cod. 10351/R - 50ml conical test tubes in PP, with red screw cap, graduated,
Cod. 10351/S - 50ml conical test tubes in PP, light blue screw cap not ins.,
Cod. 10351/SG - 50ml conical test tubes in PP, with screw cap, graduated,
Cod. 10351/SG/25 - CONICAL TEST TUBES IN PP 30X115 MM - 50 ML
Cod. 10351/SG/50/B - CONICAL TT IN PP 30X115 -50 ML BAGS OF 50 PCS- BLUE CAP
Cod. 10351/SG/CS - 50ml conical test tubes in PP, with screw cap, graduated,
Cod. 10351/TA/SG - 50ml conical test tubes in PP, light blue screw cap graduated
Cod. 10352 - 15ml conical test tubes in PP, with screw cap, graduated,
Cod. 10352/B - 15ml conical test tubes in PP, blue screw cap
Cod. 10352/E - CONICAL TT IN PP 17X120MM 15ML SCREW CAP - BAGS OF 100 PCS
Cod. 10352/E/SG - 15ml conical test tubes in PP, with screw cap and label
Cod. 10352/R - 15ml conical test tubes in PP, with red screw cap, graduated,
Cod. 10352/SG - 15ml conical test tubes in PP, with screw cap, graduated,
Cod. 10352/SG/100 - CONICAL TEST TUBES IN PP 17X120MM- 15 ML - SCREW
Cod. 10352/SG/50/B - CONICAL TT PP 17X120 - 50ML 50 PCS/BOX - BLUE CAP
Cod. 10352/SG/CS - 15ml conical test tubes in PP, with screw cap, graduated,
Cod. 10361 - 10ml cylindrical test tubes in PS, with screw cap,
Cod. 10361/B - 10ml cylindrical test tubes in PS, with white screw cap,
Cod. 10361/E - CYL. T.TUBES W/SCREW CAP IN PS DIAM. 16X100 MM VOL.10 ML WITH
Cod. 10361/E/SG - 10ml cylindrical test tubes in PS, screw cap, label, sterile
Cod. 10361/MO - 10ml cylindrical test tubes in PP, with screw cap,
Cod. 10361/MO/S - 10ml cylindrical test tubes in PP, without cap, Ø16x100mm
Cod. 10361/MO/SG - 10ml cylindrical test tubes in PP, with screw cap,
Cod. 10361/MO/SG/CS - 10ml cylindrical test tubes in PP, with screw cap,
Cod. 10361/MO/SG/TG - 10ml cylindrical test tubes in PP, with yellow screw cap,
Cod. 10361/P - 10ml cylindrical test tubes in PS, screw cap not assembled
Cod. 10361/R - 10ml cylindrical test tubes PS , red screw cap not assembled,
Cod. 10361/S - 10ml cylindrical test tubes in PS. screw cap not mounted
Cod. 10361/SG - 10ml cylindrical test tubes in PS, with screw cap,
Cod. 10361/SG/150 - 10ml cylindrical test tubes in PS, screw cap, Ø16x100mm
Cod. 10361/SG/20 - CYLINDRICAL TT 10 ML SCREW CAP 16X100 PS STERILE 20 PCS/BAG
Cod. 10361/SG/25 - 10ml cylindrical test tubes in PS, screw cap, Ø16x100mm
Cod. 10361/SG/CS - 10ml cylindrical test tubes in PS, with screw cap, Ø16x100 mm
Cod. 10362 - 15ml cylindrical test tubes in PS, with screw cap,
Cod. 10362/P - 15ml cylindrical test tubes in PS, screw cap not assembled
Cod. 10362/SG - 15ml cylindrical test tubes in PS, with screw cap,
Cod. 10362/SG/CS - 15ml cylindrical test tubes in PS, with screw cap, Ø16x120 mm
Cod. 10363 - 20ml cylindrical test tubes in PS, with screw cap,
Cod. 10363/R - 20ml cylindrical test tubes in PS, with red screw cap,
Cod. 10363/SG - 20ml cylindrical test tubes in PS, with screw cap,
Cod. 10363/SG/CS - 20ml cylindrical test tubes in PS, with screw cap, Ø16x150 mm
Cod. 1038/E - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1038/MO/E - 5ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1038/MO/T - 5ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1038/MO/T/100 - 5ml cylindrical test tubes PP Ø12x86mm, with rim and cap,
Cod. 1038/MO/T/SG - 5ml cylindrical test tubes in PP, cap
Cod. 1038/MO/TE - 5ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1038/MO/TE/SG - 5ml cylindrical test tubes in PP, with rim, cap and label,
Cod. 1038/MO/TG/E/SG - 5ml cylindrical test tubes, in PP, with rim, yellow cap and
Cod. 1038/MO/TN - 5ML CYLINDRICAL TT IN PP 12X86 GRADUATED - CAP NOT INSERTED
Cod. 1038/T - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1038/TE - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1038/TE/SG - 5ml cylindrical test tubes in PS, with rim, cap and label,
Cod. 1038/TG/E/SG - 5ml cylindrical test tubes in PS, with rim, yellow cap label
Cod. 1038/TR/E - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1040 - 120ml urine containers in PP, with self-adhesive lid, not
Cod. 1040/P - 120ml urine containers in PS, with self-adhesive lid,
Cod. 1040/P/S - 120 ml urine containers in PS, graduated, Ø73 x 66 mm,
Cod. 1040/S - 120ml urine containers in PP, without self-adhesive lid, not
Cod. 10401 - Caps in PE colour neutral, for test tubes Ø12 mm

Cod. 10402 - Caps in PE colour neutral, for test tubes Ø16 mm
Cod. 10403 - CAPS FOR T. TUBES DIAM. 14.5 MM. FOR TUBES DIAM.
Cod. 10404 - Caps in PE colour neutral, for test tubes Ø18 mm
Cod. 10405 - Caps in PE colour neutral, for test tubes Ø24 mm
Cod. 10406 - Caps in PE colour neutral, for test tubes Ø30 mm
Cod. 10407 - Caps in PE colour neutral, for test tubes Ø35 mm
Cod. 10408 - Caps in PE colour neutral, for test tubes Ø40 mm
Cod. 10409 - Caps in PE colour neutral, for test tubes Ø45 mm
Cod. 1041 - 30ml containers in PS, with white pressure cap,
Cod. 1041/E - 30ml containers in PS, with pressure cap,
Cod. 1041/S - 30ml containers in PS, without cap, Ø35 x 41 mm
Cod. 1041/SG - 30ml containers in PS, with white pressure cap,
Cod. 1041/T - 30ml containers in PS, with white inserted pressure cap,
Cod. 10410 - Caps in PE colour neutral, for test tubes Ø50 mm
Cod. 10411 - Caps in PE colour neutral, for test tubes Ø20 mm
Cod. 1045 - Cuvettes for spectrophotometer MACRO type 2 - 4 ml, in PMMA
Cod. 10450/SG - 14ml test tube with 2 position closure cap, in PS, graduated,
Cod. 10450/SG/CS - 14ml test tube with 2 position closure cap, in PS, graduated,
Cod. 1046 - Cuvettes for spectrophotometer 0.5-2ml SEMI-MICRO type, PMMA,
Cod. 10470/SG - 5ml test tubes with 2 position closure cap, in PS, graduated,
Cod. 10470/SG/25 - 5ml test tubes, PS, 2 position closure cap, graduated, Ø12x75
Cod. 10470/SG/CS - 5ml test tubes with 2 position closure cap, in PS, graduated,
Cod. 1050 - 150ml urine containers in PS, with pressure cap, graduated,
Cod. 1050/E - 150ml urine containers in PS, with pressure cap, graduated,
Cod. 1050/E/SG - 150ml urine containers in PS, pressure cap, graduated, label
Cod. 1050/S - 150ml urine containers in PS, without cap, graduated,
Cod. 1050/SG - 150ml urine containers in PS, with pressure cap, graduated,
Cod. 1050/T - 150ml urine containers in PS, with inserted pressure cap,
Cod. 1051 - 60ml sputum containers, in PS, with pressure cap,
Cod. 1051/E - 60ml sputum containers, in PS, with pressure cap,
Cod. 1051/E/SG - 60ml sputum containers, in PS, with pressure cap,
Cod. 1051/E/SG/CS - 60ml sputum containers, in PS, with pressure cap, label, sterile ind wrapped
Cod. 1051/S - 60ml sputum containers, in PS, without cap,
Cod. 1051/S/CS - 60ml sputum containers, in PS, without cap,
Cod. 1051/S/SG/CS - 60ml sputum containers, in PS, without cap,
Cod. 1051/SG - 60ml sputum containers, in PS, with pressure cap,
Cod. 1051/SG/CS - 60ml sputum containers, in PS, with pressure cap,
Cod. 1051/T - 60ml sputum containers, in PS, with pressure cap,
Cod. 1061 - 35ml containers in PS, with white pressure cap,
Cod. 1061/SG - 35ml containers in PS, with white pressure cap,
Cod. 1061/SG/CS - 35ml containers in PS, with white pressure cap, ind wrapped
Cod. 10621 - 2.000 ml securbox in PP, pressure lid, foam 10 holes, handle
Cod. 10622 - 5.000 ml securbox in PP, pressure lid, foam 99 holes, handle
Cod. 10631 - 5ml containers in PE, with screw cap, Ø21 x 30 mm
Cod. 10632 - 30ml containers in PE, with screw cap, Ø35 x 53 mm
Cod. 10633 - 90ml containers in PE, with screw cap, Ø55 x 62 mm
Cod. 1070 - 7ml containers "bijou" type, in PS, Ø20 x 50 mm,
Cod. 1070/E - 7ml containers "bijou" type, in PS, Ø20 x 50 mm,
Cod. 1070/E/SG - 7ml containers "bijou" type, in PS, Ø20x50 mm, with screw
Cod. 1070/SG - 7ml containers "bijou" type, in PS, Ø20 x 50 mm,
Cod. 10720 - Round bowls with rim, in PP, 10 liter, Ø350 x 160 mm
Cod. 1075 - 5ml cylindrical test tubes in PS, not graduated, without
Cod. 1075/250 - 5ml cylindrical test tubes PS not graduated, without rim,
Cod. 1075/C - 4.5 ml conical test tubes in PS, Ø12x75mm, not graduated
Cod. 1075/C/T - 4.5ml conical test tubes in PS, Ø12x75mm, cap
Cod. 1075/C/T/SG - 4.5 ml conical test tubes in PS, Ø12x75mm, not graduated,
Cod. 1075/E - 5ml cylindrical test tubes in PS, not graduated, without
Cod. 1075/MO - 5ml cylindrical test tubes in PP, not graduated, without
Cod. 1075/MO/250 - 5ml cylindrical test tubes PP not graduated, without rim,
Cod. 1075/MO/SG - 5ml cylindrical test tubes PP, 5ml, Ø12x75mm, Sorvall type,
Cod. 1075/MO/T - CYL. TT 5 ML 12X75 PP SORVALL TYPE W/CAP - WITHOUT RIM
Cod. 1075/MO/T/SG - 5ml cylindrical test tubes in PP, Ø12x75 mm, without
Cod. 1075/MOC - 4.5 ml conical test tubes in PP, Ø12x75mm, not graduated
Cod. 1075/S - 5ml cylindrical test tubes in PS, not graduated, without rim
Cod. 1075/SG - 5ml cylindrical test tubes PS, 5ml, Ø12x75mm, Sorvall type,
Cod. 1075/SG/50 - 5ml cylindrical test tubes PS, 5ml, Ø12x75mm, Sorvall type,
Cod. 1075/SG/CS - 5ml cylindrical test tubes PS, not graduated, without rim,
Cod. 1075/T - 5ml cylindrical test tubes in PS, not graduated, without
Cod. 1075/T/SG - 5ml cylindrical test tubes in PS, Sorvall type, without rim,
Cod. 1075/TE - 5ml cylindrical test tubes in PS, not graduated, without
Cod. 1075+1128 - 5ml cylindrical test tubes PS not graduated, Ø12x75 mm,
Cod. 1075+1128.02 - 5ml cylindrical test tubes PS not graduated, Ø12x75 mm,
Cod. 1081 - 150ml urine containers in PS, with screw cap, graduated,
Cod. 1081/CS - 150ml urine containers in PS, with screw cap, graduated,
Cod. 1081/E - 150ml urine containers in PS, with screw cap, graduated,
Cod. 1081/T - 150ml urine containers in PS, with assembled screw cap,
Cod. 10831 - Laboratory spatulas, in high impact PS, lenght 150 mm,

Cod. 10831/P - Laboratory spatulas in PP, spatula/spatula type, 150 mm
Cod. 10831/SG - Laboratory spatulas in PS type spatula+spatula 150 mm
Cod. 10831/SG/CS - Laboratory spatulas in PS, type spatula+spatula,150 mm,
Cod. 10832 - Laboratory spatulas, in high impact PS, lenght 180 mm,
Cod. 10832/P - Laboratory spatulas in PP, spatula/spatula type, 180 mm
Cod. 10832/SG - Laboratory spatulas in PP, spatula/spatula type, 180 mm, sterile
Cod. 10832/SG/CS - Laboratory spatulas, in high impact PS, lenght 180 mm,
Cod. 10833 - Laboratory spatulas, in high impact PS, lenght 180 mm,
Cod. 10833/P - Laboratory spatulas in PP, spatula/spoon type, 180 mm
Cod. 10833/SG - Laboratory spatulas in PP, spatula/spoon type, 180 mm, sterile
Cod. 10833/SG/CS - Laboratory spatulas, in high impact PS, 180mm, type spatula
Cod. 10834 - Laboratory spatulas, in high impact PS, lenght 210 mm,
Cod. 10834/P - Laboratory spatulas in PP, spatula/spoon type, 210 mm
Cod. 10834/SG - Laboratory spatulas, in high impact PS, lenght 210 mm,
Cod. 10834/SG/CS - Laboratory spatulas, in PS, lenght 210mm, spatula-spoon,
Cod. 1091 - 150ml urine containers in PS, with screw cap, graduated,
Cod. 1091/E - 150ml urine containers in PS, screw cap, graduated, label,
Cod. 111 - PETRI DISHES IN PS DIAM.90MM WITH 2 SECTORS, STERILIZED
Cod. 1120 - Square petri dishes 120x120 mm with triple vents, in PS,
Cod. 1124 - Cover for sample cups in PE, anti-evaporation, neutral,
Cod. 1126 - Cover for sample cups in PE, push-on, neutral,
Cod. 1126 - Cover for sample cups in PE, push-on, neutral,
Cod. 1127 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127* - TEST TUBES CAPS DIAM.16-W/TONGUES-LIGHT BLUE
Cod. 1127.01 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.01* - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.02 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.02* - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.03 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.03* - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.04 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.04* - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.05 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.05* - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.06 - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1127.06* - Stoppers with tongues in PE for test tubes Ø16 mm,
Cod. 1128 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.01 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.01* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.02 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.02* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.03 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.03* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.04 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.04* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.05 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.05* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.06 - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1128.06* - Stoppers with tongues in PE for test tubes Ø12 mm,
Cod. 1130 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.01 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.01* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.02 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.02* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.03 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.03* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.04 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.04* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.05 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.05* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.06 - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1130.06* - Stoppers with tongues in PE for test tubes Ø13 mm,
Cod. 1131 - 12ml special urine test tubes in PS, graduated, Ø17x105 mm,
Cod. 1131/E - 12ml special urine test tubes in PS, graduated, Ø17x105 mm,
Cod. 1131/E/S - 12ml special urine test tubes in PS, graduated, Ø17x105 mm, cap
Cod. 1131/G - 12ml urine test tubes in PS, yellow cap
Cod. 1131/S - 12ml special urine test tubes in PS, graduated, Ø17x105 mm,

Cod. 1131/S/1500 - 12ml special urine test tubes in PS, graduated, Ø17x105 mm,
Cod. 1131/T - 12ml urine test tubes in PS, cap
Cod. 1134 - Caps in PE for special urine test tubes cod. 1131/S
Cod. 1134.01 - Caps in PE for special urine test tubes cod. 1131/S
Cod. 1134.02 - Caps in PE for special urine test tubes cod. 1131/S
Cod. 11452 - 15ml conical test tubes in PS, with screw cap yellow colour,
Cod. 11452/E - 15ml conical test tubes in PS, yellow screw cap, label
Cod. 11452/S - 15ml conical test tube in PS, separated screw yellow cap
Cod. 11452/SG - 15ml conical test tubes in PS, with screw cap yellow colour,
Cod. 11452/SG/CS - 15ml conical test tubes in PS, yellow screw cap, Ø17x120 mm,
Cod. 1147 - Stoppers closed at the bottom with safety grip, in PE, for
Cod. 1147 - Stoppers closed at the bottom with safety grip, in PE, for
Cod. 1148 - Stoppers closed at the bottom with safety grip, in PE, for
Cod. 1148 - Stoppers closed at the bottom with safety grip, in PE, for
Cod. 1148BIANCO - High pressure cap for test tubes Ø12, white colour
Cod. 11581 - Centrifuge conical test tubes in PS da 13.5ml, Ø16x110 mm,
Cod. 11581/E/SG - Centrifuge conical test tubes in PS da 13.5ml, Ø16x110 mm,
Cod. 11581/SG - Centrifuge conical test tubes in PS da 13.5ml, Ø16x110 mm,
Cod. 11581/SG/450 - Centrifuge conical test tubes in PS, 13.5ml, Ø16x110, white
Cod. 11581/SG/CS - Centrifuge conical test tubes in PS da 13.5ml, Ø16x110 mm,
Cod. 11581/SG/TR - 13.5ml conical test tubes in PS, graduated, Ø16x110, red screw cap
Cod. 11581/SG/TR/450 - Centrifuge conical test tubes in PS, 13.5ml, Ø16x110, red
Cod. 11581/SGCSTR250 - Centrifuge conical test tubes in PS, 13.5ml, Ø16x110, red
Cod. 11581/TR/SG/450 - 13.5ml conical test tubes in PS, graduated, Ø16x110, red screw cap, sterile
Cod. 1164 - 2.5ml cylindrical test tubes in PS, not graduated, without
Cod. 1168 - 1 ml cylindrical test tubes in PP, no graduated, without
Cod. 11681 - Centrifuge conical test tubes in PP da 13.5ml, Ø16x110 mm,
Cod. 11681/E - Centrifuge conical test tubes in PP, 13.5ml, Ø16x110 mm,
Cod. 11681/SG - Centrifuge conical test tubes in PP da 13.5ml, Ø16x110 mm,
Cod. 11681/SG/CS - Centrifuge conical test tubes in PP da 13.5ml, Ø16x110 mm,
Cod. 1201/M - Tips MLA type in PP, vol. 101-1000 ul, neutral,
Cod. 1201/M/SG - Tips MLA type in PP, vol. 101-1000 ul, neutral,
Cod. 1202/C - Tips Eppendorf type in PP, 0,5-10 µl cristal, neutral,
Cod. 1202/C/55 - Tips Eppendorf type in PP, 0,5-10 µl cristal, neutral,
Cod. 1202/C/SG - Tips Eppendorf type in PP, 0,5-10 ul cristal, neutral,
Cod. 1202/C/SG/CS - Tips Eppendorf type in PP, 0,5-10 ul cristal, neutral, sterile ind wrapped
Cod. 1202/E - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/E/5 - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/E/500 - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/E/CS - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour, ind wrapped
Cod. 1202/E/N - Tips Eppendorf type in PP, vol. 5-200 ul, neutral colour
Cod. 1202/E/SG - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/E/SG/CS - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/EN - Tips Eppendorf type in PP, vol. 5-200 ul, neutral colour,
Cod. 1202/G - Tips Gilson type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/G/SG - Tips Gilson type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/G/SG/CS - Tips Gilson type in PP, vol. 5-200 ul, yellow colour,
Cod. 1202/M - Tips MLA type in PP, vol. 5-200 ul, neutral colour,
Cod. 1202/M/CS - Tips MLA type in PP, vol. 5-200 ul, neutral colour, ind wrapped
Cod. 1202/M/SG - Tips MLA type in PP, vol. 5-200 ul, neutral colour,
Cod. 1202/M/SG/CS - Tips MLA type in PP, vol. 5-200 ul, neutral colour,
Cod. 1202/MG - Tips Gilson type in PP, vol. 0.1-10ul, neutral colour,
Cod. 1202/MG/SG - Tips Gilson type in PP, vol. 0.1-10ul, neutral colour,
Cod. 1202/OM - Tips Oxford type in PP, vol. 5-200 ul, neutral colour,
Cod. 1202/OM/CS - Tips Oxford type in PP, vol. 5-200 ul, neutral colour, ind wrapped
Cod. 1202/OM/SG - Tips Oxford type in PP, vol. 5-200 ul, neutral colour,
Cod. 1202/OM/SG/CS - Tips Oxford type in PP, neutral colour, 5-200ul, sterile ind wrapped
Cod. 1202/U - Universal tips in PP, vol 2-200ul graduated, yellow,
Cod. 1202/U/SG - Universal tips in PP, vol 2-200ul graduated, yellow,
Cod. 1203 - 0.2ml micro test tubes in PP, with flat cap, Ø6 x 21 mm
Cod. 1203/U - Universal tips in PP, graduat. vol. 2-200 ul, neutral colour,
Cod. 1203/U/SG - Universal tips in PP, neutral colour, 2-200ul, sterile
Cod. 1204/U - Universal tip in PP, yellow colour, 2-200ul, beveled,
Cod. 1204/U/SG - Universal tips in PP, yellow colour, 2-200ul, sterile
Cod. 121 - PETRI DISHES IN PS DIAM.90MM WITH 3 SECTORS ST,BAGS 20 PCS
Cod. 1211 - 60ml faeces containers in PS, with pressure cap and spoon,
Cod. 1211/CS - STOOL CONTAINERS 60ML PS 41X57 W/PRESSURE CAP+SPOON IND.WRAPP
Cod. 1211/E/SG - 60ml faeces containers in PS, with pressure cap and spoon,
Cod. 1211/E/SG/CS - 60ml faeces containers PS with pressure cap, spoon, label,
Cod. 1211/SG - 60ml faeces containers in PS, with pressure cap and spoon,
Cod. 1211/SG/CS - 60ml faeces containers in PS, with pressure cap and spoon,
Cod. 1212 - 60ml specimen containers, in PS, with pressure cap,
Cod. 1212/CS - 60ml specimen containers in PS, pressure cap, individually wrapped

Cod. 1212/E/SG - 60ml specimen containers in PS, pressure cap, individually wrapped sterile, label
Cod. 1212/SG - 60ml specimen containers, in PS, with pressure cap,
Cod. 1212/SG/CS - 60ml specimen containers, in PS, with pressure cap,
Cod. 1213 - 60ml containers without cap, in PS, Ø41 x 55 mm
Cod. 1221 - 20ml scintillation vials in PE with screw cap, Ø27x 61 mm
Cod. 1222/RO - 4ml scintillation vials in PE, with screw cap, Ø13 x 54 mm
Cod. 1230 - 200ml urine containers in PS, with screw cap, graduated,
Cod. 1230/10 - URINE CONTAINERS VOL.200ML IN PS SCREW CAP
Cod. 1230/100 - URINE CONTAINERS VOL.200 ML IN PS SCREW CAP
Cod. 1230/CS - STERILE URINE CONTAINERS VOL 200 ML IN PS SCREW CAP IND
Cod. 1230/E - 200ml urine containers in PS, with screw cap, graduated,
Cod. 1230/E/SG - 200ml urine containers in PS, screw cap, graduated, label,
Cod. 1230/E/SG/DB - 200ml urine containers in PS, screw cap, graduated, sterile
Cod. 1230/S/E - 200ml urine containers in PS, without cap, graduated,
Cod. 1230/SG - 200ml urine containers in PS, with screw cap, graduated,
Cod. 1230/T - 200ml urine containers in PS, with assembled screw cap,
Cod. 1230/TE - 200ml urine containers in PS, inserted screw cap, graduated,
Cod. 1230/TS - 200ml urine containers in PS, with assembled screw cap,
Cod. 1230SG - 200ml urine containers in PS, with assembled screw cap, sterile
Cod. 1250 - Coulter cups for cell counters 35ml, in PS, Ø31 x 55 mm,
Cod. 1250/T - Coulter cups for cell counters 35ml, in PS, with PE cap,
Cod. 1250/T/SG - Coulter cups for cell counters 35ml, in PS, with PE cap, sterile
Cod. 12731 - Sampling tanks 2,500ml, for 24h urine collection, PE,
Cod. 12731/E - Sampling tanks 2,500ml, for 24h urine collection, PE,
Cod. 12731/E/SG - URINE CONTAINERS 24 HOURS 2500 ML-TANK IN PE W/LABEL
Cod. 12731/SAC - Sampling tanks 2,500ml, for 24h urine collection, PE,
Cod. 12731/SG - 24h urine collection tank, PE, 2,500ml, sterile ind. wrapped,
Cod. 12731K - 24h urine collection tank, PE, 2,500ml, sterile ind. wrapped,
Cod. 1302/B - Tips Biohit type in PP, vol. 2-300 ul, neutral colour,
Cod. 1302/B/SG - Tips Biohit type in PP, vol. 2-300 ul, neutral colour,
Cod. 1302/G - Tips Gilson type in PP, 2-200 ul graduated, neutral,
Cod. 1302/G/SG - Tips Gilson type in PP, 2-200 ul graduated, neutral,
Cod. 1303 - 2ml micro test tubes in PP, graduated, with cap
Cod. 1303/F - 2ml micro test tubes in PP, graduated, with cap,
Cod. 1303/SG - 2ml micro test tubes in PP, graduated, with cap, sterile
Cod. 131 - PETRI DISHES IN PS DIAM.90MM WITH 4 SECTORS STERILIZED
Cod. 13501 - Microscope slides 26x76 mm, cut type, thick 0.9/1.0 mm
Cod. 13502 - Microscope slides 26x76 mm, ground edges, thick 0.9/1.0 mm
Cod. 13503 - Microscope slides 26x76 mm, frosted end, thick 0.9/1.0 mm
Cod. 13504 - Microscope slides 26x76 mm, ground edges with frosted end,
Cod. 13551 - Microscope coloured slides, frosted end white colour,
Cod. 13552 - Microscope coloured slides, frosted end blue colour,
Cod. 13553 - Microscope coloured slides, frosted end pink colour,
Cod. 13554 - Microscope coloured slides, frosted end yellow colour,
Cod. 13555 - Microscope coloured slides, frosted end green colour,
Cod. 13556 - Microscope coloured slides, frosted end orange colour,
Cod. 13570 - Positive charge slides 26x76mm with white writing area
Cod. 13580 - Sinalized coated slides 26x76 mm, with white writing area
Cod. 1375 - 5ml cylindrical test tubes in PS, not graduated, without
Cod. 1375/E - CYLINDRICAL TT 13X75 IN PS WITH LABEL
Cod. 1375/MO - 5ml cylindrical test tubes in PP, not graduated, without
Cod. 1375/MO/T - 5ml cylindrical test tubes in PP, not graduated, with cap
Cod. 1375/MO/TE - 5ml cylindrical test tubes in PP, not graduated, with cap
Cod. 1375/S - CYLIND. TT 13X75 IN PS WITHOUT RIM - IN 1 BAG OF 4000 PIECES
Cod. 1375/T - 5 ml cylindrical test tubes, in PS, Ø13 x 75 mm,
Cod. 1375/T/E - TEST TUBES IN PS 13X75 PS W/CAP AND LABEL
Cod. 1375/T/SG - 5ML CYLINDRICAL TT W/OUT RIM W/CAP - STERILE
Cod. 14005 - Embedding cassettes, in acetal resin, white colour,
Cod. 14006 - Embedding cassettes, in acetal resin, yellow colour
Cod. 14007 - Embedding cassettes, in acetal resin, green colour,
Cod. 14008 - Embedding cassettes, in acetal resin, pink colour,
Cod. 14009 - Embedding cassettes, in acetal resin, light blue,
Cod. 14009 - Embedding cassettes, in acetal resin, light blue,
Cod. 1402/B - Tip Biohit m-LINE/PROLINE PLUS type, vol. 0.1-10ul, neutral,
Cod. 1402/B/SG - Tip Biohit m-LINE/PROLINE PLUS type, vol. 0.1-10ul, neutral,
Cod. 1402/E - Tips Eppendorf type in PP, vol. 2-20 ul, neutral colour,
Cod. 1402/E/SG - Tips Eppendorf type in PP, vol. 2-20 ul, neutral colour,
Cod. 1402/G - Tips Gilson type in PP, vol. 2-200 ul, yellow colour,
Cod. 1402/G/SG - Tips Gilson type in PP, vol. 2-200 ul, yellow colour,
Cod. 1402/MG - Tips Gilson type in PP, 0.1-10ul lengthened, neutral,
Cod. 1402/MG/SG - Tips Gilson type in PP, 0.1-10ul lengthened, neutral,
Cod. 141 - Petri dishes Ø 100 mm, in PS, without triple vents, aseptic,
Cod. 141/AN - Petri dishes Ø 100 mm, in PS, without triple vents, aseptic,
Cod. 141/CS - PETRI DISHES IN PS,DIAM.100MM, STERI.IND.WR
Cod. 141/N - Petri dishes Ø 100 mm, without triple vents, in PS,
Cod. 141/SG - Petri dishes Ø 100 mm, in PS, without triple vents, sterile,
Cod. 141/SG/AN - Petri dishes Ø 100 mm, in PS, without triple vents, sterile,

Cod. 14100 - Protective biopsy pads, 32x26 mm, in polyester foam,
Cod. 14105 - Biopsy cassettes, in acetal resin, white colour,
Cod. 14106 - Biopsy cassettes, in acetal resin, yellow colour
Cod. 14107 - Biopsy cassettes, in acetal resin, green colour,
Cod. 14108 - Biopsy cassettes, in acetal resin, pink colour,
Cod. 14109 - Biopsy cassettes, in acetal resin, light blue,
Cod. 14115 - Embedding rings in ABS, in white colour
Cod. 14116 - Embedding rings in ABS, in yellow colour
Cod. 14117 - Embedding rings in ABS, in green colour
Cod. 14118 - Embedding rings in ABS, in pink colour
Cod. 14119 - Embedding rings in ABS, in light blue colour
Cod. 14120 - 20ml surgical containers in PP yellow screw cap, graduated,
Cod. 14120/B - 20ml surgical containers in PP yellow screw cap, graduated,
Cod. 14121 - 40ml surgical containers in PP yellow screw cap, graduated,
Cod. 14121/B - 40ml surgical containers in PP yellow screw cap, graduated,
Cod. 14122 - 60ml surgical containers in PP yellow screw cap, graduated,
Cod. 14122/B - 60ml surgical containers in PP yellow screw cap, graduated,
Cod. 14123 - 90ml surgical containers in PP yellow screw cap, graduated,
Cod. 14123/B - 90ml surgical containers in PP yellow screw cap, graduated,
Cod. 14124 - 120 ml surgical containers in PP, yellow screw cap graduated
Cod. 14124/B - 120 ml surgical containers in PP, yellow screw cap graduated
Cod. 14125 - Mega embedding cassettes in acetal resin, white colour
Cod. 14126 - Mega embedding cassettes, in acetal resin, yellow colour
Cod. 14127 - Mega embedding cassettes, in acetal resin, green colour,
Cod. 14128 - Mega embedding cassettes, in acetal resin, pink colour,
Cod. 14129 - Mega embedding cassettes, in acetal resin, light blue,
Cod. 14131 - 30 ml containers for biopsy in PS, with pressure cap in PE,
Cod. 14132 - 50 ml containers for biopsy in PS, with pressure cap in PE,
Cod. 14134 - 100ml containers for biopsy in PS, with pressure cap in PE,
Cod. 14135 - Super mega cassettes, in acetal resin, white colour
Cod. 14136 - 150ml containers for biopsy in PS, with pressure cap in PE,
Cod. 14138 - 200ml containers for biopsy in PS, with pressure cap in PE,
Cod. 14140 - 250ml containers for biopsy in PS, with pressure cap in PE,
Cod. 14142 - Surgical specimen containers, in PP, with pressure cap,
Cod. 14142/B - Transparent containers in PP, for surgical specimens, 500ml,
Cod. 14142/SG - Surgical specimen containers, in PP, with pressure cap,
Cod. 14142/SG/CS - Surgical specimen containers, in PP, with pressure cap, sterile ind wrapped
Cod. 14143 - Surgical specimen containers, in PP, with pressure cap,
Cod. 14143/B - Transparent containers in PP, for surgical specimens, 1000ml
Cod. 14143/SG/CS - Transparent containers in PP, for surgical specimens, 1000ml, sterile ind wrapped
Cod. 14144 - Surgical specimen containers, in PP, with pressure cap,
Cod. 14144/B - Transparent containers in PP, for surgical specimens, 1500ml
Cod. 14144/SG/CS - Surgical specimen containers in PP, with cap, 1500ml, sterile ind wrapped
Cod. 14150 - Transparent containers in PP, for surgical specimens, 150ml,
Cod. 14150/B - Transparent containers in PP, for surgical specimens, 150ml,
Cod. 14150/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 150ml
Cod. 14151 - 250 ml surgical containers in PP, yellow screw cap graduated
Cod. 14151/B - 250 ml surgical containers in PP, yellow screw cap graduated
Cod. 14151/SG - 250 ml surgical containers in PP, green screw cap, graduated
Cod. 14152 - 500 ml surgical containers in PP, yellow screw cap graduated
Cod. 14152/B - 500 ml surgical containers in PP, yellow screw cap graduated
Cod. 14152/SG - 500 ml surgical containers in PP, green screw cap, graduated
Cod. 14153 - 1000ml surgical containers in PP, yellow screw cap graduated
Cod. 14153/B - 1000ml surgical containers in PP, yellow screw cap graduated
Cod. 14155 - Transparent containers in PP, for surgical specimens, 250ml,
Cod. 14155/B - Transparent containers in PP, for surgical specimens, 250ml,
Cod. 14155/SG - Transparent containers in PP, for surgical specimens, 250ml,
Cod. 14155/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 250ml
Cod. 14160 - Transparent containers in PP, for surgical specimens, 500ml,
Cod. 14160/S - Surgical specimen containers in PP, pressure cap, serigraphed, 500ml
Cod. 14160/SG - Transparent containers in PE, for surgical specimens, 500ml,
Cod. 14160/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 500ml
Cod. 14170 - Transparent containers in PP, for surgical specimens, 1000ml
Cod. 14170/S - Surgical specimen containers in PP, pressure cap, serigraphed, 1000ml
Cod. 14170/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 1000ml
Cod. 14175 - Transparent containers in PP, for surgical specimens, 2000ml
Cod. 14175/B - Transparent containers in PP, for surgical specimens, 2000ml
Cod. 14175/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 2300ml
Cod. 14175/T - Containers in PE for surgical specimens, 2000ml, Ø170x154mm,
Cod. 14180 - Transparent containers in PP, for surgical specimens, 3000ml

Cod. 14180/B - Transparent containers in PP, for surgical specimens, 3000ml
Cod. 14180/S - Transparent containers in PP, for surgical specimens, 3000ml
Cod. 14180/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 3000ml
Cod. 14185 - Transparent containers in PP, for surgical specimens, 5000ml
Cod. 14185/B - Transparent containers in PP, for surgical specimens, 5000ml
Cod. 14185/SG/CS - Surgical specimen containers in PP, pressure cap, sterile ind. Wrapped, 5000ml
Cod. 14190 - Big containers in PP, for surgical specimens, 5,100ml,
Cod. 14190/B - Big containers in PP, for surgical specimens, 5,500 ml,
Cod. 14190/SG/CS - Surgical specimen containers in white PP, pressure cap, sterile ind. Wrapped, 5500ml
Cod. 14192 - Big containers in PP, for surgical specimens, 2,500 ml,
Cod. 14192/B - Big containers in PP, for surgical specimens, 2,500 ml,
Cod. 14192/SG/CS - Surgical specimen containers in white PP, pressure cap, sterile ind. Wrapped, 2500ml
Cod. 14195 - Big containers in PP, for surgical specimens, 11,000ml,
Cod. 14195/B - Big containers in PP, for surgical specimens, 11,000 ml,
Cod. 14195/SG/CS - Surgical specimen containers in white PP, pressure cap, sterile ind. Wrapped, 11000ml
Cod. 14205 - Embedding cassettes, in acetal resin, white colour,
Cod. 14206 - Embedding cassettes, in acetal resin, yellow colour
Cod. 14207 - Embedding cassettes, in acetal resin, green colour,
Cod. 14208 - Embedding cassettes, in acetal resin, pink colour,
Cod. 14209 - Embedding cassettes, in acetal resin, light blue,
Cod. 14215 - Embedding cassettes without lid, white color, in POM
Cod. 14216 - Embedding cassettes without lid, yellow color, in POM
Cod. 14217 - Embedding cassettes without lid, green color, in POM
Cod. 14218 - Embedding cassettes without lid, pink color, in POM
Cod. 14220 - Stainless steel lids for standard embedding cassettes,
Cod. 14301 - Stainless steel base mould, 7 x 7 x 6 mm
Cod. 14302 - Stainless steel base mould, 15 x 15 x 6 mm
Cod. 14303 - Stainless steel base mould, 24 x 24 x 6 mm
Cod. 14304 - Stainless steel base mould, 30 x 24 x 6 mm
Cod. 14305 - Stainless steel base mould, 37 x 24 x 6 mm
Cod. 14306 - Stainless steel base mould, for mega cassettes
Cod. 14307 - Stainless steel base mould, for super mega cassettes
Cod. 14401 - Disposable base mould in PVC, 7 x 7 x 6 mm
Cod. 14402 - Disposable base mould in PVC, 15 x 15 x 6 mm
Cod. 14403 - Disposable base mould in PVC, 24 x 24 x 6 mm
Cod. 14404 - Disposable base mould in PVC, 30 x 24 x 6 mm
Cod. 14405 - Disposable base mould in PVC, 37 x 24 x 6 mm
Cod. 14406 - Disposable base mould in PVC, for mega cassettes
Cod. 14407 - Disposable base mould in PVC, for super mega cassettes
Cod. 14501 - Biopsy bags for histological processing, in polyester,
Cod. 14502 - Biopsy bags for histological processing, in polyester,
Cod. 14503 - Biopsy bags for histological processing, in polyester,
Cod. 1501 - Pasteur pipettes 1ml in PE, lenght 150 mm, graduated,
Cod. 1501/SG - Pasteur pipettes 1ml in PE, lenght 150 mm, graduated,
Cod. 1501/SG/10 - Pasteur pipettes 1ml in PE, lenght 150 mm, graduated,
Cod. 1501/SG/100 - Pasteur pipettes 1ml in PE, lenght 150 mm, graduated,
Cod. 1501/SG/CS - Pasteur pipettes 1ml in PE, lenght 150 mm, graduated,
Cod. 1502 - Pasteur pipettes 3ml in PE, lenght 150 mm, graduated,
Cod. 1502/20 - Disposable pipette pasteur 3ml
Cod. 1502/SG - Pasteur pipettes 3ml in PE, lenght 150 mm, graduated,
Cod. 1502/SG/10 - Pasteur pipettes 3ml in PE, lenght 150 mm, graduated,
Cod. 1502/SG/CS - Pasteur pipettes 3ml in PE, lenght 150 mm, graduated,
Cod. 1503 - Capillary Pasteur pipettes, lenght 150 mm, in PE,
Cod. 1503/N - Capillary Pasteur pipettes, lenght 150 mm, in PE
Cod. 1503/N* - PASTEUR PIPETTES PE CAPILLARY
Cod. 1503/SG - Capillary Pasteur pipettes, lenght 150 mm, in PE,
Cod. 1503/SG/10 - Capillary Pasteur pipettes, lenght 150 mm, in PE, sterile
Cod. 1503/SG/10/N* - STERILE PASTEUR PIPETTES PE CAPILLARY - 10 PCS/BAG
Cod. 1503/SG/CS - Capillary Pasteur pipettes, lenght 150 mm, in PE,
Cod. 1503/SG/CS/N - Capillary Pasteur pipettes, lenght 150 mm, in PE, sterile ind wrapped
Cod. 151 - Petri dishes Ø 100 mm, in PS, with triple vents, aseptic,
Cod. 151/AN - Petri dishes Ø 100 mm, in PS, with triple vents, aseptic,
Cod. 151/N - Petri dishes Ø 100 mm, with triple vents, in PS,
Cod. 151/SG - Petri dishes Ø 100 mm, in PS, with triple vents, sterile R,
Cod. 151/SG/AN - Petri dishes Ø 100 mm, in PS, with triple vents, sterile R,
Cod. 15101 - Slides for urine sedimentation in PMMA
Cod. 15102 - Kit with 100 slides for urinary sediments (10 cells) +
Cod. 15103 - Slides urinary sediments kit + Pasteur pipette + staining
Cod. 15104 - Sternheimer & Malbin staining solution for urinary sediment.
Cod. 1511 - Pasteur pipettes "fine tip", in polyethylene,
Cod. 1511/SG - Pasteur Pipettes "FINE TIPS" 5 ml, in PE, sterili
Cod. 1511/SG/CS - Pasteur Pipettes "FINE TIPS" 5 ml, in PE, sterili

Cod. 1515 - Narrow stem Pasteur pipette in PE, 4 ml, lenght 83 mm
Cod. 1515/SG - Narrow stem Pasteur pipette in PE, 4 ml, lenght 83 mm,
Cod. 1515/SG/CS - Narrow stem Pasteur pipette in PE, 4 ml, lenght 83 mm,
Cod. 1518 - Paddle Pasteur pipette in PE, 0.8 ml, lenght 125 mm
Cod. 1518/SG - Paddle Pasteur pipette in PE, 0.8 ml, lenght 125 mm,
Cod. 1518/SG/CS - Paddle Pasteur pipette in PE, 0.8 ml, lenght 125 mm,
Cod. 1519 - Paddle Pasteur pipette in PE, 1 ml, lenght 130 mm
Cod. 1519/SG - Paddle Pasteur pipette in PE, 1 ml, lenght 130 mm,
Cod. 1519/SG/CS - Paddle Pasteur pipette in PE, 1 ml, lenght 130 mm,
Cod. 1523 - Pasteur pipettes 1.5 ml, lenght 230 mm, in PE,
Cod. 1523/SG - Pasteur pipettes 1.5 ml, lenght 230 mm, in PE,
Cod. 1523/SG/20 - Pasteur pipettes 1.5 ml, lenght 230 mm, in PE,
Cod. 1523/SG/CS - Pasteur pipettes 1.5 ml, lenght 230 mm, in PE,
Cod. 1526 - Gilford sample cups 0.5ml, in PP, Ø10 x 22 mm
Cod. 15361 - 10ml cylindrical test tubes in PS, screen-printed graduation,
Cod. 15361/MO - 10ml cylindrical test tubes in PP, screen-printed graduation,
Cod. 15361/SG - 10ml cylindrical test tubes in PS, screen-printed graduation,
Cod. 15361/SG/CS - 10ml cylindrical test tubes PS screen-printed graduation, cap
Cod. 15362 - 15ml cylindrical test tubes in PS, with screw cap, serigraphed
Cod. 15362/SG - 15ml cylindrical test tubes in PS, serigraphed, Ø16x120, screw cap, sterile
Cod. 15362/SG/CS - 15ml cylindrical test tubes in PS, serigraphed, Ø16x120, screw cap, sterile ind wrapped
Cod. 155 - Contact petri dishes Ø 55 mm, with triple vents, in PS,
Cod. 155/N - Petri dishes contact type Ø55mm, not sterile
Cod. 1560 - 30 ml sputum containers in PP, with screw cap, neutral color,
Cod. 1560/SG - 30 ml sputum containers in PP, with screw cap, neutral color,
Cod. 1601 - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 1602 - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 1602/SG - REFILLS FOR UNIVERSAL BOXES W/96 YELLOW TIPS, EPPEND.TYPE
Cod. 1603 - Tips Eppendorf type in PP, vol. 2-20 ul, neutral colour,
Cod. 161 - Petri dishes Ø 60 mm, with triple vents, in PS,
Cod. 161/N - Petri dishes Ø 60 mm, with triple vents, in PS,
Cod. 1625 - 4 ml cylindrycal test tubes flat bottom, in PS, graduated,
Cod. 1625/MO - 4 ml cylindrycal test tubes flat bottom, in PP, graduated,
Cod. 1630 - 250ml containers Ø58x119mm, in PS, alluminium screw cap with
Cod. 1630/E - 250ml containers Ø58x119mm, in PS, alluminium screw cap with
Cod. 1630/E/SG - 250ml containers in PS with metallic lid, label, sterile
Cod. 1630/E/TS - 250ml containers Ø58x119mm, in PS, alluminium screw cap with
Cod. 1630/SG - 250ml containers in PS with metallic lid, sterile
Cod. 1630/TS - 250ml containers Ø58x119mm, in PS, alluminium screw cap with
Cod. 1650.01 - 20ml cylindrical test tubes in PS blue colour, not graduated,
Cod. 1650.02 - 20ml cylindrical test tubes in PS red colour, not graduated,
Cod. 1650.03 - 20ml cylindrical test tubes in PS green colour, not graduated
Cod. 1675 - 8ml cylindrical test tubes in PS, with rim, graduated,
Cod. 1675/MO - 8ml cylindrical test tubes in PP, with rim, graduated,
Cod. 1675MO+1147+CUP - Kit test tube Ø16x75 in PP + white stopper safety grip +
Cod. 1702 - Tips Eppendorf type in PP, 0,5-10 ul cristal, neutral,
Cod. 1801 - Tips Gilson type in PP, vol. 100-1000 ul, blue colour,
Cod. 1802 - Tips Gilson type in PP, vol. 5-200 ul, yellow colour,
Cod. 1803 - Tips Gilson type in PP, 2-200 ul graduated, neutral,
Cod. 1804 - Tips Gilson type in PP, vol. 2-200 ul, yellow colour
Cod. 181 - Petri dishes Ø 120 mm, without triple vents, in PS,
Cod. 181/N - Petri dishes Ø 120 mm, without triple vents, in PS,
Cod. 181/SG - Petri dishes Ø 120 mm, without triple vents, in PS,
Cod. 18100 - Cuvette 12 segments COBAS MIRA MIRA PLUS type autoanalyzer
Cod. 18101 - Cuvette 12 segments Cobas Mira and MiraPlus type, in PMMA
Cod. 18138 - 10ml conical urine test tube, cap and label, PS, Ø16x100mm
Cod. 18139 - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 18139 - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 18139200 - 120ml urine containers in PP, with device for vacuum tube,
Cod. 18140 - Faeces container with pressure cap and spoon, PS, 60ml, 41x57
Cod. 1851 - Universal tips in PP, vol. 100-1000 ul, blue colour,
Cod. 1852 - Universal tips in PP, vol 2-200ul graduated, yellow,
Cod. 18600 - Multicell cuvettes for Konelab
Cod. 1902 - Tips Gilson type in PP, vol. 0.1-10ul, neutral colour,
Cod. 1902/SG - REFILLS FOR UNIVERSAL BOXES W/96 TIPS GILSON P2 AND P10 01
Cod. 1903 - Tips Gilson type in PP, 0.1-10ul, lengthened, neutral,
Cod. 195 - Contact petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 1951 - Tips Biohit type in PP, vol. 2-300 ul, neutral colour,
Cod. 1954 - Tips for Biohit m-Line/Proline Plus, 0,1-10ul, neutral, refill
Cod. 19550 - Urine containers for testing drugs abuse, with seal cap,
Cod. 1970 - Tips Eppendorf type in PP, 20-300ul graduated, neutral,
Cod. 19702 - Tips for gel loading in PP, vol. 0.1-200 ul, neutral,
Cod. 19720 - Tips for gel loading 0.1-20 ul with filter, in neutral PP,
Cod. 19730 - Tips for gel loading 0.1-100ul with filter, in neutral PP,

Cod. 1975 - Tips Oxford type in PP, vol. 5-200 ul, neutral colour,
Cod. 1980 - Tips MLA type in PP, vol. 5-200 ul, neutral colour,
Cod. 2000 - Test tubes in PP with K2 EDTA, for 2.5ml of blood, Ø12x56 mm,
Cod. 2000/1 - Test tubes with K2 EDTA for 1ml of blood, paediatric use,
Cod. 2000/1/V - Test tubes with K2 EDTA for 1ml of blood, paediatric use,v
Cod. 2001 - Test tubes in PP with K2 EDTA, for 2.5ml of blood, Ø16x60 mm,
Cod. 2002 - Test tubes in PP with K2 EDTA, for 5ml of blood, Ø16 x 60 mm,
Cod. 2003 - Test tubes in PP with K2 EDTA, for 2.5ml of blood, Ø12x86 mm,
Cod. 2004 - Test tubes in PP with K2 EDTA, for 5ml of blood, Ø12 x 86 mm,
Cod. 2005 - Test tubes in PP with K2 EDTA, for 2.5ml of blood, Ø13x75 mm,
Cod. 2006 - K2 EDTA IN 16X100 CYL. TT FOR 5ML OF
Cod. 2007 - Test tubes in PP with K2 EDTA, for 10ml of blood, Ø16x100 mm,
Cod. 2008 - Test tubes in PP with K2 EDTA, for 4ml of blood, Ø13x75 mm,
Cod. 2015 - Blood grouping plates in PS, 10 wells, 160 x 40 x 6 mm
Cod. 2030 - 30ml specimen containers, in PP, with inserted screw cap
Cod. 2030/E - 30ml specimen containers in PP, screw cap, label
Cod. 2030/E/SG - 30ml specimen containers, PP, with inserted red screw cap,
Cod. 2030/P - 30ml specimen containers in PP , with not inserted screw cap
Cod. 2030/S - 30ml specimen containers, in PP, Ø35 x 38 mm,
Cod. 2030/S/R - 30ml specimen containers, in PP, Ø35 x 38 mm,
Cod. 2030/SG - 30ml specimen containers, in PP, with inserted screw cap
Cod. 2030/TS - 30ml specimen containers in PP, screw cap, label, sterile ind wrapped
Cod. 20351 - 50ml conical test tubes in PP, screw cap, graduated Ø30x115mm
Cod. 20351/E/SG - 50ml sterile conical test tube screw cap, graduated Ø30x115mm
Cod. 20351/P - 50ml conical test tubes in PP, screw cap not assemb.,Ø30x115,
Cod. 20351/R - 50ml conical test tubes in PP, with red screw cap, graduated,
Cod. 20351/S - 50ml conical test tubes in PP, without cap, Ø30x115mm,
Cod. 20351/SG - 50ml conical test tubes in PP, screw cap, graduated Ø30x115mm
Cod. 20351/SG/50/B - CON.TT PP 30X115-50ML BLUE CAP W/SELFSTANDING BASE-50 PCS/BOX
Cod. 20351/SG/CS - 50ml conical test tubes in PP, screw cap, graduated Ø30x115mm
Cod. 2040 - 60ml specimen containers, in PS, with inserted screw cap
Cod. 2040/B - 60ml specimen containers, in PS, with white inserted
Cod. 2040/E - 60ml specimen containers, in PS, with inserted screw cap
Cod. 2040/E/R - 60ml specimen containers, in PS, inserted red screw cap,
Cod. 2040/E/SG - 60ml specimen containers, PS, with screw cap and label,
Cod. 2040/E/TS - 60ml specimen containers, in PS, with inserted screw cap
Cod. 2040/EB/TS - 60ml specimen containers, PS, inserted white screw cap
Cod. 2040/EST/SG - 60ml specimen containers, PS, with screw cap and label,
Cod. 2040/P - 60ml specimen container in PS, Ø35 x 70 mm,
Cod. 2040/P/E - 60ml specimen container in PS, Ø 35 x 70 mm, with label,
Cod. 2040/R - 60ml specimen containers, in PS, with red inserted
Cod. 2040/SG - 60ml specimen containers, in PS, with screw cap,
Cod. 2040/TS - 60ml specimen containers, in PS, with inserted screw cap
Cod. 2040/TS/70 - SPECIMEN CONT. 60ML 35X70MM PS STERILE - BAGS OF 70 PCS
Cod. 2042 - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2042/E - SPECIMEN CONTAINERS 60 ML 35X70 IN PS SCREW CAP
Cod. 2042/E/TS - SPECIMEN CONTAINERS IN PS 60 ML, SCREW CAP W/SPOON
Cod. 2042/SG - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2050 - 60ml PP graduated specimen containers inserted screw cap
Cod. 2050/100 - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2050/B - 60ml specimen containers, in blue PP, with inserted
Cod. 2050/B/SG - 60ml specimen containers, in blue PP, with screw cap,
Cod. 2050/C - CAPS FOR SPECIMEN CONTAINERS YELLOW SCREW CAP, FOR ITEM
Cod. 2050/CS - 60ml PP graduated specimen container , inserted screw cap
Cod. 2050/DDK - 60ml specimen containers in PP with red inserted screw cap
Cod. 2050/E - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2050/E/S - 60ml specimen containers, in PP, with not inserted screw cap
Cod. 2050/E/SG - 60ml specimen containers, PP, with screw cap and label.
Cod. 2050/E/TS - 60ml specimen containers, PP, with screw cap and label,
Cod. 2050/P - 60ml specimen container in PP, Ø35 x 70 mm, graduated,
Cod. 2050/P/E - 60ml specimen container in PP, graduated, Ø35x70 mm, label,
Cod. 2050/PA/20/SG - 60ml specimen containers, PP, grad, lightblue screw cap not
Cod. 2050/PB/20/SG - 60ml specimen containers, PP, graduated, blue screw cap not
Cod. 2050/PR - 60ml specimen containers, in PP, Ø35 x 70 mm. with
Cod. 2050/PR/20/SG - 60ml specimen containers, PP, graduated, red screw cap not
Cod. 2050/R - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2050/R/WHITE - 60ml containers in WHITE PP, inserted screw cap red colour,
Cod. 2050/S - 60ml specimen containers, in PP, with screw cap,
Cod. 2050/SG - 60ml specimen containers, in PP, with screw cap,
Cod. 2050/SG/C25 - SPECIMEN CONTAINERS 60 ML. IN PP STERILIZED, PACK
Cod. 2050/SG/CS - 60ml specimen containers in PP, screw cap, label, sterile ind wrapped
Cod. 2050/SG/S - 60ml specimen containers in PP, screw cap, label, sterile ind wrapped
Cod. 2050/T - 60ml specimen containers in PP, screw cap, label

Cod. 2050/TA/20/SG - 60ml specimen containers, PP, lightblue screw cap assembled,
Cod. 2050/TA/SG/20 - 60ml specimen containers, in PP, light blue screw cap,
Cod. 2050/TAPPO/B - Screw cap for containers cod 2050
Cod. 2050/TB/20/SG - 60ml specimen containers, PP, blue screw cap assembled,
Cod. 2050/TR/20/SG - 60ml specimen containers, PP, red screw cap assembled,
Cod. 2050/TS - 60ml specimen containers, in PP, with screw cap,
Cod. 2050/WHITE/TB - 60ml PP WHITE specimen containers, BLUE screw cap
Cod. 2050P - 60ml specimen containers, in PP, with not inserted
Cod. 2052 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/10 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/100 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/CS - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/E - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/E/CS - 60ml faeces containers in PP, with screw cap and spoon, confezione singola
Cod. 2052/E/SG - 60ml faeces containers in PP, with screw cap, spoon, label
Cod. 2052/E/TS - STER.SPECIMEN CONTAINER 60 ML 35x70 IN PP W/SCREW CAP
Cod. 2052/R - 60ml faeces containers in PP, with red screw cap inserted
Cod. 2052/SG - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/SG/25 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2052/SG/C10 - STOOL CONTAINERS 60 ML. SCREW CAP W/SPOON IN PP
Cod. 2052/SG/C100 - STOOL CONTAINER 60 ML. SCREW CAP W/SPOON IN PP
Cod. 2052/T5 - 60ml faeces containers in PP.
Cod. 2052/TS - 60ml faeces containers in PP.
Cod. 2062 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2062/10 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2062/E/SG - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2062/P - 60ml faeces containers in PP, with separated screw cap
Cod. 2062/SG - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2072 - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2072/E/SG - 60ml faeces containers in PS, screw cap and spoon, label,
Cod. 2072/P - 60ml faeces containers in PS, with separated screw cap
Cod. 2072/SG - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2083654 - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 2100 - Test tubes in PP with K3 EDTA, for 2.5ml of blood, Ø12x56 mm,
Cod. 2100/1 - Test tubes with K3 EDTA for 1ml of blood, paediatric use,
Cod. 2100/1/V - Test tubes in PP Ø12x56mm, with K3EDTA, for 1ml of blood
Cod. 2100/TM - Test tubes in PP with K3 EDTA for 2,5ml of blood 15x56mm
Cod. 2101 - Test tubes in PP with K3 EDTA, for 2.5ml of blood, Ø16x60 mm,
Cod. 2102 - Test tubes in PP with K3 EDTA, for 5ml of blood, Ø16 x 60 mm,
Cod. 2103 - Test tubes in PP with K3 EDTA, for 2.5ml of blood, Ø12x86 mm,
Cod. 2104 - Test tubes in PP with K3 EDTA, for 5ml of blood, Ø12 x 86 mm,
Cod. 2105 - Test tubes in PP with K3 EDTA, for 2.5ml of blood, Ø13x75 mm,
Cod. 2105/TM - Test tubes in PP with K3 EDTA, for 2.5ml of blood, Ø13x75 mm,
Cod. 2105/VIOLA - Test tubes in PP with K3 EDTA, for 2.5ml of blood, Ø13x75 mm,
Cod. 2106 - K3 EDTA IN 16X100 CYL. TT FOR 5 ML. OF
Cod. 2107 - Test tubes in PP with K3 EDTA, for 10ml of blood, Ø16x100 mm,
Cod. 2108 - Test tubes in PP with K3 EDTA, for 4ml of blood, Ø13x75 mm,
Cod. 2108/5 - test tube in PP with K3 EDTA for 5 ml of blood 13x75
Cod. 2108/TM - Test tubes in PP with K3 EDTA, for 4ml of blood, Ø13x75 mm,
Cod. 2108/VIOLA - Test tubes in PP with K3 EDTA, for 4ml of blood, Ø13x75 mm,
Cod. 2120 - 150ml urine containers in PP, with screw cap not inserted,
Cod. 2120/100 - 150ml urine container in PP, screw cap
Cod. 2120/50 - 150ml urine containers in PP, screw cap not inserted, grad.,
Cod. 2120/B - 150ml urine containers in PP, with white screw cap not
Cod. 2120/B/SG - 150ml urine containers in PP, white screw cap, graduated,
Cod. 2120/CS - 150ml urine containers in PP, with screw cap, graduated,
Cod. 2120/CS/M - 150ml urine containers in PP, screw cap, graduated, aseptic,
Cod. 2120/CS/MI - 120ml urine containers in PP, with screw cap, graduated,
Cod. 2120/E - 150ml urine containers in PP, with screw cap not inserted,
Cod. 2120/E/CS - 150ml urine containers in PP, screw cap, graduated, label,
Cod. 2120/E/SG - 150ml urine containers in PP, screw cap, graduated, label
Cod. 2120/E/TS - STER. URINE CONTAINERS VOL 150 ML IN PP W/SCREW CAP
Cod. 2120/E/TSB - 150 ml urine containers in PP, screw cap, sterile, label
Cod. 2120/ES - URINE CONTAINERS 150 ML PP SCREW CAP W/LABEL
Cod. 2120/ES/SG - URINE CONTAINER 150 ML PP SCREW AP W/LABEL NOT INSERTED
Cod. 2120/H/SG - 150 ml urine containers in PP, screw cap with groove, gradua.
Cod. 2120/N - 150ml urine containers in PP, with neutral screw cap not
Cod. 2120/R - 150ml urine containers in PP, with red screw cap not
Cod. 2120/S - 150ml urine containers in PP, without cap, graduated,
Cod. 2120/SG - 150ml urine containers in PP, with screw cap, graduated,
Cod. 2120/SG/10 - 150ml urine container in PP, screw cap, sterile ind wrapped
Cod. 2120/SG/25 - Urine container 150ml in PP, screw cap, graduated, sterile
Cod. 2120/SG/C10 - URINE CONTAINERS GRADUATED 150 ML. GRADUATED SCREW CAP IN
Cod. 2120/SG/C30 - URINE CONTAINERS GRADUATED 150 ML. GRADUATED, SCREW CAP I

Cod. 2120/SG/MI - 120ml urine containers in PP, with screw cap, graduated,
Cod. 2120/SG+1118 - 150ml urine container in PP, screw cap, sterile ind wrapped + label
Cod. 2120/T - 150ml urine containers in PP, with inserted screw cap,
Cod. 2120/T/100 - 150ml urine containers in PP, inserted screw cap, Ø58x72 mm
Cod. 2120/T/N - 150ml urine container in PP, screw cap neutral colour
Cod. 2120/T5 - 150ml urine containers in PP, inserted screw cap, graduated,
Cod. 2120/T50 - URINE CONTAINERS VOL.150 ML-IN PP-W/SCREW CAP
Cod. 2120/TA/SG - 150ml urine containers PP with light blue screw cap, graduat.
Cod. 2120/TB - 150ml urine containers in PP, with inserted white screw cap,
Cod. 2120/TE - 150ml urine containers PP with inserted light blue screw cap,
Cod. 2120/TN - 150ml urine containers in PP, with inserted neutral screw
Cod. 2120/TR - 150ml urine containers in PP, with inserted red screw cap,
Cod. 2120/TS - 150ml urine containers in PP, with screw cap, graduated,
Cod. 2120/TSG - STERILE URINE CONTAINER 150 ML PP - SCREW YELLOW CAP
Cod. 2120/TV - 150ml urine containers PP with green screw cap not inserted,
Cod. 2120/V/500 - 150ml urine containers in PP, green screw cap not inserted,
Cod. 2122 - URINE CONTAINER IN PP 150 ML WITH SPOON
Cod. 2122/SG - STERILE URINE CONTAINER 150ML IN PP SCREW CAP + SPOON
Cod. 2200 - Test tubes with KF+NA2 EDTA, in PP, for 2.5 of blood, with
Cod. 2200/G - KF+NA2 EDTA IN TT 12X56 FLAT BOTTOM YELLOW CAP FOR 2,5 ML
Cod. 2201 - Test tubes with KF+NA2 EDTA, in PP, for 2.5 of blood, with
Cod. 2201/G - KF+NA2 EDTA 16X60 FLAT BOTTOM TT - YELLOW - FOR 2,5ML OF
Cod. 2202 - Test tubes with KF+NA2 EDTA, in PP, for 5 of blood, with
Cod. 2202/G - FLOURIDE OXALATE IN TT 16X60 FLAT BOTTOM- YELLOW CAP - 5 M
Cod. 2203 - Test tubes with KF+NA2 EDTA, in PP, for 2.5 of blood, with
Cod. 2204 - Test tubes with KF+NA2 EDTA, in PP, for 5 of blood, with
Cod. 2205 - Test tubes with KF+NA2 EDTA, in PP, for 2.5 of blood, with
Cod. 2205/TG - Test tubes with KF+NA2 EDTA, in PP, for 2.5 of blood, with
Cod. 2206 - KF + NA2 EDTA IN 16X100 CYL. TT FOR 5 ML OF
Cod. 2207 - Test tubes with KF+NA2 EDTA, in PP, for 10 of blood, with
Cod. 2208 - Test tubes with KF+NA2 EDTA, in PP, for 4 of blood, with
Cod. 221 - Petri dishes Ø 140 mm, with triple vents, in PS,
Cod. 221/N - Petri dishes Ø 140 mm, with triple vents, in PS,
Cod. 2220 - 200ml urine containers in PP, with screw cap, graduated,
Cod. 2220/250 - 200ml urine containers in PP, with screw cap, graduated,
Cod. 2220/CS - 200ml urine containers in PP, with screw cap, graduated,
Cod. 2220/E - 200 ml urine containers in PP, screw cap, with label,
Cod. 2220/E/CS - 200ml urine containers in PP, screw cap, graduated, label,
Cod. 2220/E/SG - 200ml urine containers in PP, screw cap, graduated, label
Cod. 2220/E/TS - 200ml urine containers in PP, inserted screw cap, graduated
Cod. 2220/E/TSB - 200ml urine container in PP, screw cap, label, boric acid
Cod. 2220/R - 200ml urine containers in PP screw red cap. graduated,
Cod. 2220/S - 200 ml urine container in PP, graduated, without cap
Cod. 2220/SG - 200ml urine containers in PP, with screw cap, graduated,
Cod. 2220/T - 200ml urine containers in PP, with inserted screw cap,
Cod. 2220/TS - 200ml urine containers in PP, with inserted screw cap,
Cod. 2250 - Specimen containers in PP, 40 ml, with screw cap
Cod. 2250/E/SG - 40ml specimen containers in PP with screw cap and label.
Cod. 2250/SG - 40ml specimen containers in PP with screw cap,
Cod. 2300 - Test tubes with Sodium Heparin in PP, for 2.5 of blood,
Cod. 2301 - Test tubes with Sodium Heparin in PP, for 2.5 of blood,
Cod. 2302 - Test tubes with Sodium Heparin in PP, for 5 of blood,
Cod. 2303 - Test tubes with Sodium Heparin in PP, for 2.5 of blood,
Cod. 2304 - Test tubes with Sodium Heparin in PP, for 5 of blood,
Cod. 2305 - Test tubes with Sodium Heparin in PP, for 2.5 of blood,
Cod. 2306 - SODIUM HEPARIN IN 16X100 CYL. TT, FOR 5ML OF
Cod. 2307 - Test tubes with Sodium Heparin in PP, for 10 of blood,
Cod. 2308 - Test tubes with Sodium Heparin in PP, for 4 of blood,
Cod. 231 - Petri dishes Ø 150 mm, with triple vents, in PS,
Cod. 231/N - Petri dishes Ø150mm, not sterile, with vents
Cod. 2400 - Test tube with Lithium Heparin in PP, for 2.5 of blood,
Cod. 2400/1 - Test tube with Lithium Heparin for 1ml of blood, paediatric
Cod. 2400/TV - LITHIUM HEPARIN IN 12X56 FLAT BOTTOM TT FOR 2,5ML OF BLOOD
Cod. 2401 - Test tube with Lithium Heparin in PP, for 2.5 of blood,
Cod. 2402 - Test tube with Lithium Heparin in PP, for 5 of blood,
Cod. 2403 - Test tube with Lithium Heparin in PP, for 2.5 of blood,
Cod. 2404 - Test tube with Lithium Heparin in PP, for 5 of blood,
Cod. 2404/TV - Test tubes in PP with Lithium heparin, Ø12x86mm, for 5ml of blood
Cod. 2404/VERDE - LITHIUM HEPARIN - GREEN CAP IN CYL.T.T. FOR 5 ML OF BLOOD
Cod. 2405 - Test tube with Lithium Heparin in PP, for 2.5 of blood,
Cod. 2405/TV - Test tube with Lithium Heparin in PP, for 2.5 of blood,
Cod. 2406 - LITHIUM HEPARIN IN 16X100 CYL. TT., FOR 5ML.
Cod. 2407 - Test tube with Lithium Heparin in PP, for 10 of blood,

Cod. 2408 - Test tube with Lithium Heparin in PP, for 4 of blood,
Cod. 2408/VERDE - LITHIUM HEPARIN IN 13X75 CYL.TT FOR 5 ML OF
Cod. 2420 - 150ml urine containers in PP, with screw cap and plug,
Cod. 2420/E/SG - 150ml urine containers in PP, with screw cap and plug,
Cod. 2420/R - 150ml urine containers in PP, with red screw cap and plug,
Cod. 2420/SG - 150ml urine containers in PP, screw cap and plug, graduated,
Cod. 2420/TR - 150ml urine containers in PP, with inserted red screw cap
Cod. 2440 - 60ml specimen containers, in PS, with inserted screw cap
Cod. 2440/CS - 60ml specimens container in PS, screw cap, ind wrapped
Cod. 2440/E - 60ml specimen containers, in PS, with inserted screw cap
Cod. 2440/E/CS - 60ml specimen containers, in PS with screw cap and label
Cod. 2440/E/SG - 60ml specimen containers, PS, with screw cap and label
Cod. 2440/P - 60ml specimen containers, in PS, not inserted screw cap,
Cod. 2440/SG - 60ml specimen containers, in PS, with screw cap,
Cod. 2442 - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2442/E - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2442/E/SG - 60ml faeces containers in PS, with screw cap, spoon, label,
Cod. 2442/R - 60ml faeces containers in PS, with inserted red screw cap
Cod. 2442/SG - 60ml faeces containers in PS, with screw cap and spoon,
Cod. 2450 - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2450/B - 60ml specimen containers in PP with inserted white screw cap,
Cod. 2450/CS - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2450/E - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2450/E/SG - 60ml specimen containers, PP, with screw cap and label
Cod. 2450/E/TS - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2450/P - 60ml specimen containers, in PP, Ø38 x 65 mm,
Cod. 2450/R - 60ml specimen containers, in PP, with inserted red screw
Cod. 2450/SG - 60ml specimen containers, in PP, with screw cap,
Cod. 2450/SG/100 - 60ml specimen containers, in PP, with screw cap,
Cod. 2450/TS - 60ml specimen containers, in PP, with inserted screw cap
Cod. 2452 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2452/E - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2452/E/CS - 60ml Faeces container in PP, screw cap and spoon, label, ind wrapped
Cod. 2452/E/SG - 60ml faeces containers in PP, with screw cap, spoon, label,
Cod. 2452/E/TS - STER.SPEC.CONTAINER IN PP 38x65 60 ML WITH SCREW
Cod. 2452/R - 60ml faeces containers in PP, with red screw cap and spoon,
Cod. 2452/SG - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2452/SG/100 - 60ml faeces containers in PP, with screw cap and spoon,
Cod. 2452/T/5 - 60 ml faeces containers in PPm
Cod. 2500 - Test tubes in PP with K3 EDTA, for 3ml of blood, Ø13 x 75 mm,
Cod. 2500* - K3 EDTA - PERFORABLE CAP
Cod. 2500/N - Test tubes in PP with K3 EDTA, for 3ml of blood, Ø13 x 75 mm,
Cod. 2500/N* - Test tubes in PP with K3 EDTA, for 3ml of blood, Ø13 x 75 mm,
Cod. 2500/NEUTRO - K3 EDTA-PIERCEABLE NEUTRAL CAP IN 13X75 TT FOR 3 ML OF BLOOD
Cod. 2500/SE - Test tubes in PP with K3 EDTA, for 3ml of blood without label
Cod. 2500/SE/V - Test tubes in PP with K3 EDTA, for 3ml blood, without label,
Cod. 2500/V - Test tubes in PP with K3 EDTA, for 3ml of blood, Ø13 x 75 mm,
Cod. 2500/V* - Test tubes in PP with K3 EDTA, for 3ml of blood, Ø13 x 75 mm,
Cod. 2500/V/2 - Test tubes in PP with K3 EDTA, rubber violet pierceable cap,
Cod. 2500/V/SG - Test tubes in PP. K3 EDTA, 3ml of blood, Ø13x75.sterile
Cod. 2500/VIOLA - K3EDTA- PIERCEABLE VIOLET CAP IN 13x75 TT FOR 3 ML OF BLOOD
Cod. 2501 - Test tubes with 0.4ml Sodium Citrate for coagulation, in PP
Cod. 2502 - Test tubes with 0.4ml Sodium Citrate for coagulation, in PP
Cod. 2503 - 0.4ML SODIUM CITRATE YELLOW CAP IN 16X100 CYL. TEST TUBE
Cod. 2505 - 0.4ML SODIUM CITRATE YELLOW CAP IN 12X56 FLAT BOTTOM TT.
Cod. 2505/1 - Test tube with 0,1ml Sodium Citrate for coagulation yellow
Cod. 2508 - Test tubes with 0.4ml Sodium Citrate for coagulation, in PP
Cod. 2508/BLU - SODIUM CITRATE 0,4ML BLUE CAP IN TT 13X75 FOR COAGULATION
Cod. 251 - Petri dishes Ø 90 mm, with 2 sectors, triple vents,
Cod. 251/AN - Petri dishes Ø 90 mm, with 2 sectors, triple vents,
Cod. 251/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 251/SG - Petri dishes Ø 90 mm, with 2 sectors, triple vents,
Cod. 251/SG/AN - Petri dishes Ø 90 mm, with 2 sectors, triple vents,
Cod. 251/SG/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 2510 - 0.5 ML SODIUM CITRATE YELLOW CAP IN 12X56 FLAT BOTTOM TT
Cod. 2511 - Test tubes with 0.5ml Sodium Citrate for coagulation, in PP
Cod. 2512 - Test tubes with 0.5ml Sodium Citrate for coagulation, in PP
Cod. 2512/TB - Test Tube with 0.5 ml Sodium Citrate for coagulation, in PP
Cod. 2513 - 0.5ml Sodium Citrate in test tube in PP Ø16x100, yelow cap,
Cod. 2515 - 0,5 ML SODIUM CITRATE YELLOW CAP IN 13X75 CYL. T.T.
Cod. 2515/BLU - 0.5 ml Sodium Citrate in test tube PP Ø13x75, blue cap,
Cod. 2515/TB/F - Test tubes with 0.5ml Sodium Citrate, in PP
Cod. 2520 - Test tubes with 0.25ml Sodium Citrate for coagulation, in PP
Cod. 2520/TB - Test tube with 0,25ml Sodium Citrate with blue cap in PP

Cod. 2520/TR - Test tubes with 0.25ml Sodium Citrate for coag, pink in PP
Cod. 2521 - Test tubes with 0.25ml Sodium Citrate for coagulation, in PP
Cod. 2522 - Test tubes with 0.25ml Sodium Citrate for coagulation, in PP
Cod. 2522/R - Test tubes with 0.25ml Sodium Citrate for coagulation, in PP
Cod. 2525 - Test tubes with 0.25ml Sodium Citrate for coagulation, in PP
Cod. 2525/2 - Test tubes with 0.2ml Sodium Citrate for coagulation, in PP
Cod. 2525/32/BLU - Test tubes with 0.25ml Sodium Citrate 3.2% for coagulation,
Cod. 2580 - 30ml specimen containers, in PS, with inserted screw cap
Cod. 2580/B - 25ml specimen containers, in PS, inserted white screw cap,
Cod. 2580/B/SG - 25ml specimen containers, in PS, inserted white screw cap,
Cod. 2580/E - 25ml specimen containers, in PS, with inserted screw cap
Cod. 2580/E/CS - 25ml specimen containers in PS, screw cap, label, ind wrapped
Cod. 2580/E/P - UNIVERSAL CONTAINER PS 25ML W/SCREW CAP NOT INSER.+LABEL
Cod. 2580/E/P/W - UNIVERSAL CONTAINER PS 25 ML W/SCREW CAP NOT INSERTED+LABEL
Cod. 2580/E/SG - 25ml specimen containers, PS, with screw cap and label,
Cod. 2580/E/SG/B - 25ml specimen containers, PS, screw WHITE cap and label,
Cod. 2580/E/SG/CS - 25ml specimen containers, PS, with screw cap and label,
Cod. 2580/E/SG/CS/W - 25ml specimen containers, PS, with screw cap and label,
Cod. 2580/E/TS - SPECIMEN CONTAINER 25 ML 25X80 IN PS SCREW CAP
Cod. 2580/E/TS/W - 25ml faeces containers in PS, with inserted screw cap and
Cod. 2580/E/W - SPECIMEN CONTAINER 25 ML PS - WITH LABEL
Cod. 2580/EB - UNIVERSAL CONTAINER 30ML SCREW CAP + LABEL
Cod. 2580/EB/TS - SPECIMEN CONTAINER 25 ML 25X80 IN PS SCREW CAP
Cod. 2580/EB/TS/W - 25ml faeces containers in PS, with white screw cap,
Cod. 2580/ER - SPECIMEN CONTAINERS 25 ML, DIM. Ø25x80 MM
Cod. 2580/EST/SG - 25ml specimen containers, PS, with screw cap and label,
Cod. 2580/P - 25ml specimen containers, PS, with not inserted screw cap
Cod. 2580/PB - 25ml specimen containers, PS, with not inserted screw cap
Cod. 2580/S - 25ml specimen containers in PS, without cap
Cod. 2580/SG - 30ml specimen containers, in PS, with screw cap
Cod. 2580/SG/CS - 30ml specimen containers, in PS, with screw cap
Cod. 2580/TAPPO/A - Screw cap for 2580/2680
Cod. 2580/TB/SG/CS - 25ml specimen containers, in PS, with white screw cap,
Cod. 2580/TBIANCO - Screw cap for 2580/2680
Cod. 2580/TS - SPEC.CONTAINER CONT. 30 ML IN PS STERILE
Cod. 2580/TS/W - 25ml specimen containers, in PS, with white screw cap
Cod. 2580/W - 25 ml specimen containers, in PS, Ø 25 X 90 mm
Cod. 2580P - 25ml specimen containers, in PS, with not inserted
Cod. 2588 - 25ml faeces containers in PS, with screw cap and spoon,
Cod. 2588/E - 25ml faeces containers in PS, with screw cap and spoon,
Cod. 2588/E/CS - 25ml faeces containers in PS, with screw cap and spoon,
Cod. 2588/E/SG - 25ml faeces containers in PS, with screw cap, spoon, label
Cod. 2588/E/SG/CS - 25ml faeces containers in PS, with screw cap, spoon, label
Cod. 2588/E/SG/CS/W - STOOL CONTAINER 25 ML IN PS W/SPOON AND SCREW CAP
Cod. 2588/E/TS - SPECIMEN CONTAINER 25 ML 25X80 IN PS SCREW CAP
Cod. 2588/E/TS/W - 25ml faeces containers in PS, with screw cap and spoon,
Cod. 2588/EB - UNIVERSAL CONTAINER 30ML SCREW CAP+LABEL AND SPOON
Cod. 2588/EB/TS - SPECIMEN CONTAINER 25 ML 25X40 IN PS SCREW CAP
Cod. 2588/EB/TS/W - SPECIMENT CONTAINER 25 ML PS W/SCREW CAP + PLAIN LABEL
Cod. 2588/P - SPECIMENT CONTAINER 25 ML PS W/SCREW CAP + PLAIN LABEL
Cod. 2588/SG - 25ml faeces containers in PS, with screw cap and spoon,
Cod. 2588/SG/CS - 25ml faeces containers in PS, with screw cap and spoon,
Cod. 2588P - Spoon in polypropylene for faeces, white colour
Cod. 2600 - Test tubes with 0.25ml Sodium Citrate for E.S.R., in PP
Cod. 2600/1 - Paediatric test tubes with Sodium Citrate for 1ml blood,
Cod. 2600/TN - test tubes with 0,25ml Sodium Citrate with black cap in PP
Cod. 2601 - Test tubes with 0.25ml Sodium Citrate for E.S.R., in PP
Cod. 2602 - Test tubes with 0.25ml Sodium Citrate for E.S.R., in PP
Cod. 2603 - 0.25ML SODIUM CITRATE PINK/CAP IN 16X100 CYLINDRICAL TT.
Cod. 2605 - Test tubes with 0.25ml Sodium Citrate for E.S.R., in PP
Cod. 261 - Petri dishes Ø 90 mm, with 3 sectors, triple vents,
Cod. 261/AN - Petri dishes Ø 90 mm, with 3 sectors, triple vents,
Cod. 261/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 261/SG - Petri dishes Ø 90 mm, with 3 sectors, triple vents,
Cod. 261/SG/AN - Petri dishes Ø 90 mm, with 3 sectors, triple vents,
Cod. 261/SG/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 2610 - Test tubes with 0.4ml Sodium Citrate for E.S.R., in PP
Cod. 2610/G - Test Tubes 0,4ml Sodium yellow cap Citrate for E.S.R. in PP
Cod. 2611 - Test tubes with 0.4ml Sodium Citrate for E.S.R., in PP
Cod. 2612 - Test tubes with 0.4ml Sodium Citrate for E.S.R., in PP
Cod. 2613 - 0.4ML SODIUM CITRATE PINK CAP IN 16X100 CYLIND. T.T.
Cod. 2615 - Test tubes with 0.4ml Sodium Citrate for E.S.R., in PP
Cod. 2615/TN - Test tubes with 0.4ml Sodium Citrate for ESR, in PP
Cod. 2620 - Test tubes with 0.5ml Sodium Citrate for E.S.R., in PP

Cod. 2621 - Test tubes with 0.5ml Sodium Citrate for E.S.R., in PP
Cod. 2622 - Test tubes with 0.5ml Sodium Citrate for E.S.R., in PP
Cod. 2625 - Test tubes with 0.5ml Sodium Citrate for E.S.R., in PP
Cod. 2632 - Test tubes Ø12x56mm in PP with 0.25ml Sodium Citrate for 1ml
Cod. 2635 - Test tubes Ø13x75mm in PP with 0.4ml Sodium Citrate for 1.6ml
Cod. 2640 - 60 ml containers Ø39x60mm, in PS, alluminium screw cap with
Cod. 2640/E - 60 ml containers Ø39x60mm, in PS, alluminium screw cap with
Cod. 2640/E/SG - 60 ml specimen container in PS, metallic screw cap, label, sterile
Cod. 2640/E/TS - 60 ml containers Ø39x60mm, in PS, alluminium screw cap with
Cod. 2640/SG - 60 ml specimen container in PS, metallic screw cap, sterile
Cod. 2640/TS - 60 ml containers Ø39x60mm, in PS, alluminium screw cap with
Cod. 2661/E/TB - 10ml test tube with separating gel + clot acc., in PP, with
Cod. 2662/E - 10ml test tube with separating gel + clot acc., in PP, with
Cod. 2662/E/TB - 10ml test tube with separating gel + clot acc., in PMMA, with
Cod. 2662/TB - TT WITH SEP.SILICONE GEL+CLOT ACCEL. IN PMMA 16X100 LOW STOP
Cod. 2662/TM - TT WITH SEP.SILICONE GEL+CLOT ACCEL. IN PMMA 16X100 LOW STOP
Cod. 2663/E/TB - 5ml test tubes with separating gel + clot acc., in PP, with
Cod. 2664/E/TB - Test tubes in PP Ø12x86mm, with granules + clot activator
Cod. 2665/E - 5ml test tubes with separating gel + clot acc., in PP, with
Cod. 2665/E/TB - 5ml test tubes with separating gel + clot acc., in PMMA, with
Cod. 2665/TB - Test tubes in PMMA Ø13x75mm, with gel + clot activator
Cod. 2666/E - SILICONE GEL+CLOT ACCELERATOR IN 16X100 PP TT W/LABEL FOR 10
Cod. 2666/E/TB - 10ml test tube with separating gel + clot acc., in PP, with
Cod. 2666/TB - 10ml test tube with separating gel + clot acc., in PP, with
Cod. 2668/E - 5ml test tubes with separating gel + clot acc., in PP, with
Cod. 2668/E/TB - 5ml test tubes with separating gel + clot acc., in PMMA, with
Cod. 2668/TB - SILICONE GEL+CLOT ACCELERATOR IN PMMA 12X86 TT FOR 5ML OF
Cod. 2678/E/TB - 5ml test tubes with separating gel + clot accellerator, in PP
Cod. 2680 - 25ml specimen containers, in PP, with inserted screw cap
Cod. 2680/E - 25ml specimen containers, in PP, with inserted screw cap
Cod. 2680/E/SG - 25ml specimen containers, PP, with screw cap and label,
Cod. 2680/E/SG/CS - 25ml specimen containers, PP, with screw cap and label,
Cod. 2680/E/TS - 25ml specimen containers, PP, with screw cap and label,
Cod. 2680/EB/TS - 25ml specimen containers, PP, white inserted screw cap
Cod. 2680/EST/SG - 25ml specimen containers, PP, with screw cap and label,
Cod. 2680/P - 25ml specimen containers, in PP, with not inserted
Cod. 2680/S - 25 ml Specimen containers in PP, without cap
Cod. 2680/SG - 25ml specimen containers, in PP, with screw cap
Cod. 2680/SG/CS - 25ml specimen containers, in PP, with screw cap
Cod. 2680/TS - SPECIMEN CONTAINERS 25 ML 25X80 IN PP W/SCREW CAP
Cod. 2688 - 25ml faeces containers in PP, with screw cap and spoon,
Cod. 2688/E - 25ml faeces containers in PP, with screw cap and spoon,
Cod. 2688/E/CS - 25ml faeces containers in PP, with screw cap and spoon,
Cod. 2688/E/SG - 25ml faeces containers in PP, with screw cap, spoon, label
Cod. 2688/E/SG/CS - 25ml faeces containers in PP, with screw cap, spoon, label
Cod. 2688/E/TS - 25ml faeces containers in PP, with inserted screw cap and,
Cod. 2688/SG - 25ml faeces containers in PP, with screw cap and spoon,
Cod. 2688/SG/CS - 25ml faeces containers in PP, with screw cap and spoon,
Cod. 2700 - Test tube with 0.3ml of Sodium Citrate Ø13x75, light blue cap
Cod. 2700/2 - Test tubes in PP with 0,2ml of sodium citrate, with pierceable cap
Cod. 2705 - Test tubes in PP with 0,35ml Sodium Citrate, blue cap
Cod. 271 - Petri dishes Ø 90 mm, with 4 sectors, triple vents,
Cod. 271/AN - Petri dishes Ø 90 mm, with 4 sectors, triple vents,
Cod. 271/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 271/SG - Petri dishes Ø 90 mm, with 4 sectors, triple vents,
Cod. 271/SG/AN - Petri dishes Ø 90 mm, with 4 sectors, triple vents,
Cod. 271/SG/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 2710 - Test tubes with 0.25ml Sodium Citrate, Ø12x56, 2 blood level
Cod. 2711 - Test tubes with 0.25ml Sodium Citrate, Ø16x60, 2 blood level
Cod. 2712 - Test tubes with 0.25ml Sodium Citrate, Ø12x86, 2 blood level
Cod. 2715 - Test tubes with 0.25ml Sodium Citrate, Ø13x75, 2 blood level
Cod. 30001 - No additive plain vacuum tube, in PET, 2.0 ml, Ø13 x 75 mm,
Cod. 30002 - No additive plain vacuum tube, in PET, 3.0 ml, Ø13 x 75 mm,
Cod. 30003 - No additive plain vacuum tube, in PET, 4.0 ml, Ø13 x 75 mm,
Cod. 30004 - No additive plain vacuum tube, in PET, 6.0 ml, Ø13 x 100 mm,
Cod. 30011 - Gel+clot activator vacuum tube vol. 3.5 ml, in PET Ø13x75 mm,
Cod. 30012 - Gel+Clot activator vacuum tube vol. 5 ml, in PET, Ø13x100 mm,
Cod. 30013 - Gel+Clot activator vacuum tube vol. 8 ml, in PET, Ø16x100 mm,
Cod. 30014 - Rapid Gel + Clot act. vacuum tube, vol. 4 ml, PET, Ø13x75mm
Cod. 30020 - Clot activator vacuum tube in PET, vol. 2 ml, Ø13x75 mm,
Cod. 30021 - Clot activator vacuum tube in PET, vol. 4 ml, Ø13x75 mm,
Cod. 30022 - Clot activator vacuum tube in PET, vol. 6 ml, Ø13x100 mm,
Cod. 30023 - Clot activator vacuum tube in PET, vol. 9 ml, Ø16x100 mm,
Cod. 30031 - Gel+clot activator vacuum tube vol. 3.5 ml, in PET Ø13x75 mm,

Cod. 30032 - Gel+Clot activator vacuum tube vol. 5 ml, in PET, Ø13x100 mm,
Cod. 30033 - Gel+Clot activator vacuum tube vol. 8 ml, in PET, Ø16x100 mm,
Cod. 30100 - K2 EDTA vacuum tubes in PET, vol. 2 ml, Ø13 x 75 mm,
Cod. 30101 - K2 EDTA vacuum tubes in PET, vol. 3 ml, Ø13 x 75 mm,
Cod. 30102 - K2 EDTA vacuum tubes in PET, vol. 4 ml, Ø13 x 75 mm,
Cod. 30103 - K2 EDTA vacuum tubes in PET, vol. 6 ml, Ø13 x 100 mm,
Cod. 30104 - K2 EDTA vacuum tubes in PET, vol. 9 ml, Ø16 x 100 mm,
Cod. 30200 - K3 EDTA vacuum tubes in PET, vol. 2 ml, Ø13 x 75 mm,
Cod. 30200/1 - K3 EDTA vacuum tubes in PET, vol. 1 ml, Ø13 x 75 mm,
Cod. 30201 - K3 EDTA vacuum tubes in PET, vol. 3 ml, Ø13 x 75 mm,
Cod. 30202 - K3 EDTA vacuum tubes in PET, vol. 4 ml, Ø13 x 75 mm,
Cod. 30203 - K3 EDTA vacuum tubes in PET, vol. 6 ml, Ø13 x 100 mm,
Cod. 30204 - K3 EDTA vacuum tubes in PET, vol. 9 ml, Ø16 x 100 mm,
Cod. 3024 - URINE-CONTROL ind. Cased 24h urine bottles in PE,
Cod. 3024/GRFAR - 24h graduated urine bottles 2500ml, PE,
Cod. 3024/PRONTO - 24h graduated urine bottles 2500ml, PE,
Cod. 3024/PRONTO - 24h graduated urine bottles 2500ml, PE,
Cod. 3024/SG - URIN-CONTROL 24 HOURS URIN.COLL.CONT.IN PE
Cod. 3024/T/ASCO - 24h graduated urine tank, 2500ml, PE,
Cod. 3030/SG - URIN-TEST sterile ind. Cased 130ml urine containers in PS,
Cod. 30300 - ESR vacuum tube in PET, with 3,8% 4NC, vol. 1.6ml, Ø13x75mm
Cod. 3031/SG - URIN-TEST sterile ind. Cased 12ml urine test tubes in PS,
Cod. 3031/SG/FARMA - Urine test tube with pressure cap, PS, 12ml, Ø17x105mm
Cod. 3031/SG/GRFAR - Urine test tube with pressure cap, PS, 12ml, Ø17x105mm
Cod. 3031/SGPRONTO - Urine test tube with pressure cap, PS, 10ml, Ø16x100mm
Cod. 3039/SG - 10ml conical test tubes in PP, Ø16x100mm, graduated, red cap,
Cod. 3039/SG/PPC - 10ml cylindrical test tubes in PP Ø16x100 graduated, red cap,
Cod. 3039/SG/PS - 10ml conical test tubes in PS, Ø16x100mm, graduated, red cap,
Cod. 3039/TA/SG - 10ml conical test tube Ø16x100 PP, graduated, light blue cap,
Cod. 3039/TA/SG/PS - 10ml conical test tubes in PS, Ø16x100 graduated, l.blue cap,
Cod. 30500 - 3,2% 9NC vacuum tube in PET, vol. 2.7 ml, Ø13 x 75 mm,
Cod. 30500/38 - 3,8% 9NC vacuum tube in PET, vol. 2.7 ml, Ø13 x 75 mm,
Cod. 3050089000000 - 24h graduated urine container 2500ml, PE,
Cod. 30501 - 3,2% 9NC vacuum tube in PET, vol. 3.6 ml, Ø13 x 75 mm,
Cod. 30501/38 - 3,8% 9NC vacuum tube in PET, vol. 3.6 ml, Ø13 x 75 mm,
Cod. 30503 - 3,2% 9NC vacuum tube in PET, vol. 2 ml, Ø13 x 75 mm,
Cod. 30503/38 - 3,8% 9NC vacuum tube in PET, vol. 2 ml, Ø13 x 75 mm,
Cod. 3052/SG - BIO-TEST sterile ind. Cased 60ml faeces containers in PP,
Cod. 3052/SG/GRFAR - Faeces container with screw cap and spoon, PP, 60ml, 35x70
Cod. 3052/SG/LFH - Faeces container with screw cap and spoon, PP, 60ml Ø35x70
Cod. 3052/SGCAVA - Faeces container with screw cap and spoon, PP, 60ml, 35x70
Cod. 3052/SGPRONTO - Faeces container with screw cap and spoon, PP, 60ml, 35x70
Cod. 30600 - Glucose NH+NF vacuum tube in PET, vol. 2 ml, Ø13 x 75 mm,
Cod. 30601 - Glucose NH+NF vacuum tube in PET, vol. 4 ml, Ø13 x 75 mm,
Cod. 30800 - Lithium Heparin vacuum tube in PET, vol. 2 ml, Ø13 x 75 mm,
Cod. 30801 - Lithium Heparin vacuum tube in PET, vol. 4 ml, Ø13 x 75 mm,
Cod. 30802 - Lithium Heparin vacuum tube in PET, vol. 6 ml, Ø13 x 100 mm,
Cod. 30900 - Gel+Lithium Heparin vacum tube vol. 4 ml, in PET, Ø13x75 mm,
Cod. 30901 - Gel+Lithium Heparin vacum tube vol. 5 ml, in PET, Ø13x100 mm,
Cod. 309251 - Urine cont. 200ml PS screw cap + urine test tube PS 12ml, cap
Cod. 309253 - Faeces container with screw cap, spoon, PP, 60ml, Ø35x70mm
Cod. 309343 - Urine test tube with pressure cap, PS, 10ml, Ø16x100 mm,
Cod. 309346 - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 31 - Petri dishes Ø 35 mm, with triple vents, in PS,
Cod. 31/N - Petri dishes Ø 35 mm, with triple vents, in PS,
Cod. 3120/SG - URIN-TEST sterile ind. Cased 150ml urine containers in PP,
Cod. 3120/SG/20 - 150ml sterile urine containers in PP, screw cap, graduated,
Cod. 3120/SG/20 - 150ml sterile urine containers in PP, screw cap, graduated,
Cod. 3120/SG/GRFAR - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 3120/SG/LFH - Graduated urine container PP, screw cap red colour, 150ml,
Cod. 3120/SG/PHA - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 3120/SGCAVA - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 3120/SGPRONTO - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 31300 - Holder in PP for vacuum collection needle
Cod. 3211/SG - BIO-TEST sterile ind. Cased 60ml faeces containers in PS,
Cod. 35100 - Vacuum urine test tube 9 ml, PET, conical bottom, Ø16x100,
Cod. 35120/SG - 120ml urine containers in PP, with device for vacuum tube,
Cod. 35120/SG/PRONTO - 120ml urine containers in PP, with device for vacuum tube,
Cod. 35150 - Vacuum urine test tube 9 ml, PET, round bottom, Ø16x100 mm,
Cod. 35200 - Vacuum urine test tube 9ml,PET conical bottom with boric acid
Cod. 35250 - Vacuum urine test tube 9ml,PET round bottom, with boric acid,
Cod. 3553/E - 10ml test tubes with clot accellerator, in PMMA, with
Cod. 3553/E - 10ml test tubes with clot accellerator, in PMMA, with
Cod. 3555/E - 4ml test tubes with clot accellerator, in PMMA, with
Cod. 3556/E - 10ml test tubes with clot accellerator, in PP, with
Cod. 3558/E - 5ml test tubes with clot accellerator, in PMMA, with
Cod. 36005 - K2EDTA+Gel, vacuum tubes, PET, vol. 5 ml, Ø13 x 100 mm,
Cod. 3731 - URINE-CONTROL ind. Cased 24h urine tanks in PE,

Cod. 3731/CAVA - Tanks in PE for 24 hours urine collection, 2500ml, graduated,
Cod. 3731/GRFAR - Tanks in PE for 24 hours urine collection, 2500ml, graduated,
Cod. 3771/E/TB - 10ml test tube with separating gel, in PP, with label,
Cod. 3772/E/TB - 5ml separating gel test tubes in PP, with label, Ø13x75 mm,
Cod. 3773/E - 10ml test tube with separating gel, in PP, with red cap,
Cod. 3773/E/TB - 10ml test tube with separating gel, in PMMA, with brown cap,
Cod. 3773/TB - 10ml test tube with separating gel, in PMMA, with brown cap,
Cod. 3774/E/TB - 5 ml test tube with separating gel, in PP, with label,
Cod. 3775/E - 5ml test tubes with separating gel, in PP, with red cap,
Cod. 3775/E/TB - 5ml test tubes with separating gel, in PMMA, with brown cap,
Cod. 3776/E - SILICONE GEL IN 16X100 PP TT W/LABEL FOR 10
Cod. 3776/E/TB - 10ml test tube with separating gel, in PP, with brown cap,
Cod. 3776/TB - 10ml test tube with separating gel, in PP, with brown cap,
Cod. 3778 - SILICONE GEL IN 12X86 SPECIAL MAT. TT, FOR
Cod. 3778/E - 5ml test tubes with separating gel, in PP, with red cap,
Cod. 3778/E/TB - 5ml test tubes with separating gel, in PMMA, with brown cap,
Cod. 4001/E - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 4001/E/SG - Tips Eppendorf type in PP, vol. 100-1000ul, blue colour,
Cod. 4001/G - Tips Gilson type in PP, vol. 100-1000 ul, blue colour,
Cod. 4001/G/SG - Tips Gilson type in PP, vol. 100-1000 ul, blue colour,
Cod. 4001/U - Universal tips in PP, vol. 100-1000ul, blue colour,
Cod. 4001/U/SG - Universal tips in PP, vol. 100-1000 ul, blue colour,
Cod. 4001/UN - Universal tips 50-100ul, graduated, neutral, rack of 96 pcs
Cod. 4001/UN/SG - Universal tips in PP, vol. 50-1000 ul, neutral colour,
Cod. 4002/U - Tips Eppendorf type in PP, 20-300ul graduated, neutral,
Cod. 4002/U/SG - Tips Eppendorf type in PP, 20-300ul graduated, neutral,
Cod. 4202/B/SG - STER.PIPETTE TIPS-RACK W/LID VOL. 1-300 ul NEUTRAL, STERILE
Cod. 4202/C - Tips Eppendorf type in PP, 0,5-10 ul cristal, neutral,
Cod. 4202/C/SG - Tips Eppendorf type in PP, 0,5-10 ul cristal, neutral,
Cod. 4202/E - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 4202/E/SG - Tips Eppendorf type in PP, vol. 5-200 ul, yellow colour,
Cod. 4202/G - Tips Gilson type in PP, vol. 5-200 ul, yellow colour,
Cod. 4202/G/SG - Tips Gilson type in PP, vol. 5-200 ul, yellow colour,
Cod. 4202/M - Tips MLA type in PP, vol. 5-200 ul, neutral colour,
Cod. 4202/M/SG - Tips MLA type in PP, vol. 5-200 ul, neutral colour,
Cod. 4202/MG - Tips Gilson type in PP, vol. 0.1-10ul, neutral colour,
Cod. 4202/MG/SG - Tips Gilson type in PP, vol. 0.1-10ul, neutral colour,
Cod. 4202/OM - Tips Oxford type in PP, vol. 5-200 ul, neutral colour,
Cod. 4202/OM/SG - Tips Oxford type in PP, vol. 5-200 ul, neutral colour,
Cod. 4202/U - Universal tips in PP, vol 2-200ul graduated, yellow,
Cod. 4202/U/SG - Universal tips in PP, vol 2-200ul graduated, yellow,
Cod. 4203/U - Universal tips 2-200ul, graduated, neutral, rack of 96 pcs
Cod. 4203/U/SG - Universal tips 2-200ul, graduated, neutral, rack of 96 pcs, sterile
Cod. 4204/U - Universal tips in PP, yellow, Vol. 2-200ul, not graduated,
Cod. 4204/U/SG - Universal tips in PP, yellow, Vol. 2-200ul, not graduated,
Cod. 4302/B - Tips Biohit type in PP, vol. 2-300 ul, neutral colour,
Cod. 4302/B/SG - Tips Biohit type in PP, vol. 2-300 ul, neutral colour,
Cod. 4302/G - Tips Gilson type in PP, 2-200 ul graduated, neutral,
Cod. 4302/G/SG - Tips Gilson type in PP, 2-200 ul graduated, neutral,
Cod. 4302/U - Universal tips 2-200ul, graduated, neutral, rack of 96 pcs
Cod. 4402/B - Tips Biohit m-Line/Proline type, vol. 0.1-10ul, neutral
Cod. 4402/B/SG - Tips Biohit m-Line/Proline type, vol. 0.1-10ul, neutral
Cod. 4402/E - Tips Eppendorf type in PP, vol. 2-20 ul, neutral colour,
Cod. 4402/E/SG - Tips Eppendorf type in PP, vol. 2-20 ul, neutral colour,
Cod. 4402/G - Tips Gilson type in PP, vol. 2-200 ul, yellow colour,
Cod. 4402/G/SG - Tips Gilson type in PP, vol. 2-200 ul, yellow colour,
Cod. 4402/MG - Tips Gilson type in PP, 0.1-10ul lengthened, neutral,
Cod. 4402/MG/SG - Tips Gilson type in PP, 0.1-10ul lengthened, neutral,
Cod. 4875/E - 5ml test tubes with separating granules+clot acc, in PMMA,
Cod. 4876/E - 5ml test tubes with separating granules+clot acc, in PP,
Cod. 4876/E/TB - Test tubes Ø13x75 mm in PP with granules+clot activator
Cod. 4876/ETB - 5ml test tubes with separating granules+clot acc, in PP,
Cod. 4876/TR/E - 5ml test tubes with separating granules+clot acc, in PP,
Cod. 4878/E - 5ml test tubes with separating granules+clot acc, in PP,
Cod. 4878/TR/E - 5ml test tubes with separating granules+clot acc, in PP,
Cod. 4883/E - 6ml test tube with separating granules + clot accelerat, PP,
Cod. 4883/E/TN - 6ml test tube with separating granules + clot accelerat, PP,
Cod. 4884/E - 10ml test tube with separating granules+clot acc, in PMMA,
Cod. 4885 - 10ml test tube with separating granules+clot acc, in PS,
Cod. 4885/E - 10ml test tube with separating granules+clot acc, in PS,
Cod. 4885/R - T.T. W/SEPAR. GRANULES+CLOT AC CELER. PS FOR 10ML-RED CAP
Cod. 4886/E - 10ml test tube with separating granules+clot acc, in PP,
Cod. 4886/TR/E - 10ml test tube with separating granules+clot acc, in PP,
Cod. 4888/E - 5ml test tubes with separating granules+clot acc, in PMMA,
Cod. 4888/EB - 5ml test tubes with separating granules+clot acc, in PMMA,
Cod. 500 - Positive charge slides 26x76mm MasterGlass,

Cod. 5001/F - Macro tips Finnpipette type, vol. 500-5,000 ul, neutral,
Cod. 5001/F/SG - Macro tips Finnpipette type, vol. 500-5.000 ul, neutral,
Cod. 5001/O - Macro tips Gilson type, vol. 1,000-5,000 ul, blue,
Cod. 5001/O/SG - Macro tips Gilson type, vol. 1,000-5,000 ul, blue,
Cod. 5001/ON - Macro tips Eppendorf type, vol. 1,000-5,000 ul, neutral,
Cod. 5001/ON/SG - Macro tips Eppendorf type, vol. 1,000-5,000 ul, neutral,
Cod. 5002/U - Tips in kit Eppendorf type, vol. 2-300 ul, neutral colour,
Cod. 5003 - 0.75ml micro test tube in HDPE with cap, Ø 7.65 x 35.50 mm,
Cod. 5003/B - 0.75ml micro test tube in HDPE with cap, Ø 7.65 x 35.50 mm,
Cod. 5003/G - 0.75ml micro test tube in HDPE with cap, Ø 7.65 x 35.50 mm,
Cod. 5003/R - 0.75ml micro test tube in HDPE with cap, Ø 7.65 x 35.50 mm,
Cod. 5005 - 10ml cylindrical test tubes in PS, without rim, not
Cod. 5005/C - 10ml conical test tubes in PS, not graduated, without rim,
Cod. 5005/C/S - 10ml conical test tubes in PS, not graduated, without rim,
Cod. 5005/MO - 10ml cylindrical test tubes in PP, without rim, not
Cod. 5005/MO/S - 10ml cylindrical test tubes in PP, without rim, not
Cod. 5005/MO/T - 10ml cylindrical test tubes in PP, without rim, not
Cod. 5005/MOC - 10ml conical test tubes in PP, not graduated, without rim,
Cod. 5005/MOC/S - 10ml conical test tubes in PP, not graduated, without rim,
Cod. 5005/MOC/T - 10ml conical test tubes in PP, without rim, no graduated, cap
Cod. 5005/S - 10ml cylindrical test tubes in PS, without rim, not
Cod. 5005/S/K - 10ml cylindrical test tubes in PS, without rim, not
Cod. 5005/S/K/100 - 10ml cylindrical test tubes in PS, without rim, not graduated
Cod. 5005/S/TE - CYLINDRICAL TT 10 ML 16X100 PS NOT GRADUATED WITH CAP+LABEL
Cod. 5006 - 3ml cylindrical test tubes in PS, not graduated,
Cod. 5006/C/T - Cylindrical test tubes in PS, Ø11.5x55, cap
Cod. 5006/MO - 3ml cylindrical test tubes in PP, not graduated,
Cod. 5006/T - Cylindrical test tubes in PS, Ø11.5x55, cap
Cod. 5006T - 3ml cylindrical test tubes in PS not graduated, with cap,
Cod. 5015 - Caps in PE 10x10 mm, for cuvettes spectrophotometer
Cod. 5015/SG - Caps in PE 10x10 mm, for cuvettes spectrophotometer,
Cod. 5018 - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 5018/1000 - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 5018/MO - 5ml cylindrical test tubes in PP, with rim, graduated,
Cod. 5018/MO/1000 - 5ml cylindical test tubes in PP, graduated
Cod. 5024 - Sampling bottles 2,500ml, for 24h urine collection, PE,
Cod. 5024/E - URINE CONTAINERS "24 HOURS"VOL.2500ML SAMPLING
Cod. 5024/E/SG - STER.URINE CONTAINERS "24 HOURS"VOL 2500 ML IN PE
Cod. 5024/F - URINE CONTAINERS "24 HOURS"VOL 2500 ML IN PE
Cod. 5024/SG - STERILE URINE CONTAINERS '24 HOURS' VOL. 2500 ML. IN PE
Cod. 5024K - STER.URINE CONTAINERS "24 HOURS"VOL 2500 ML IN PE
Cod. 50351 - 50ml conical test tubes in PP, with screw cap, graduated
Cod. 50351/SG - 50ml conical test tubes in PP, with screw cap, graduated
Cod. 50351/SG/CS - 50ml conical test tube PP with cap, graduated serigraphed,
Cod. 50352 - 15ml conical test tubes in PP, with screw cap, graduated
Cod. 50352/SG - 15ml conical test tubes in PP, with screw cap, graduated
Cod. 50352/SG/CS - 15ml conical test tube PP with cap, graduated serigraphed,
Cod. 5038/E - 5ml cylindrical test tubes in PS, with rim, graduated,
Cod. 5038/MO/E - 5ml cylindrical test tubes in PP, with rim, graduated,
Cod. 5096/C - Microtiter plate lid in PS, 86x128 mm
Cod. 5096/C/SG - Microtiter plate lid in PS, 86x128 mm, sterile ind wrapped
Cod. 5096/P - Microtiter plate in PS with 96 wells flat bottom, 86x128 mm
Cod. 5096/P/SG - Microtiter plate in PS with 96 wells flat bottom, 86x128 mm
Cod. 5096/P/SG+COP - Microtiter plate in PS with 96 wells flat bottom, 86x128 mm + lid
Cod. 5096/P+COP - Microtiter plates in PS, flat bottom, 96 wells, lid
Cod. 5096/U - Microtiter plate in PS with 96 wells U bottom shape, 86x128mm
Cod. 5096/U/25 - MICROTITER PLATES IN PS."U"BOTTOM PKT OF 25PCS
Cod. 5096/U/25/SG - MICROTITER PLATES PS "U"BOTTOM STERILE PKT 25PCS
Cod. 5096/U/5 - MICROTITER PLATES IN PS "U" BOTTOM - BAGS OF 5 PCS
Cod. 5096/U/SG - Microtiter plate in PS with 96 wells U bottom shape, 86x128mm
Cod. 5096/U/SG+COP - Microtiter plate in PS with 96 wells U bottom shape, 86x128mm + lid
Cod. 5096/U+COP - Microtiter plates in PS, "U" shape bottom, 96 wells, lid
Cod. 5096/V - Microtiter plate in PS with 96 wells V bottom shape, 86x128mm
Cod. 5096/V/SG - Microtiter plate in PS with 96 wells V bottom shape, 86x128mm
Cod. 5096/V/SG+COP - Microtiter plates in PS, "V" shape bottom, 96 wells, sterile + lid
Cod. 5101/E - Tips in kit Eppendorf type, vol. 100-1000 ul, blue colour,
Cod. 5101/U - Tips in kit Universal type, vol. 100-1000 ul, blue colour,
Cod. 5112 - 3ml flat bottom test tubes in PS, graduated, with rim,
Cod. 5112/E - 3ml flat bottom test tubes in PS, graduated, with rim,
Cod. 5112/MO - 3ml flat bottom test tubes in PP, graduated, with rim,
Cod. 5112/MO/E - 3ml flat bottom test tubes in PP, graduated, with rim,
Cod. 5112/MO/T - 3ml flat bottom test tubes in PP, graduated, with rim,
Cod. 5112/MO/T/P - 3ml flat bottom test tubes in PP, graduated, with rim,
Cod. 5112/MO/TAL - 3ml flat bottom test tubes in PP, graduated, with rim,
Cod. 5112/MO/TE - 3ml flat bottom test tubes in PP, graduated, with rim,

Cod. 5112/MOR - 3ml flat bottom test tubes in Random PP, graduated,
Cod. 5112/T - 3ml flat bottom test tubes in PS, graduated, with rim,
Cod. 5112/T/100 - 3ml flat bottom cylindrical test tubes, in PS, Ø12x56 mm,
Cod. 5112/TE - 3ml flat bottom test tubes in PS, graduated, with rim,
Cod. 5120 - 120ml urine containers in PP with screw cap with device for
Cod. 5120/CS - 120ml urine containers in PP, screw cap with device x vacuum
Cod. 5120/E/SG - 120ml urine container in PP, screw cap with device for vacuum tube, label, sterile
Cod. 5120/E/TS - 120ml urine container in PP, screw cap with device for vacuum tube, label, sterile
Cod. 5120/SG - 120ml urine containers in PP, screw cap with device x vacuum
Cod. 5120/TS - 120ml urine containers in PP with screw cap with device for
Cod. 5122 - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122* - VACUTAINER TEST TUBES CAPS IN PE FOR T.T. Ø 12 MM BLUE
Cod. 5122.01 - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.01* - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.02 - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.02* - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.03 - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.03* - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.04 - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.04* - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.05 - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.05* - External caps for vacuum test tubes Ø12-13 mm, in PE,
Cod. 5122.XX - Caps for closure vacuum tube Ø12-13mm
Cod. 5122.XX* - Caps for closure vacuum tube Ø12-13mm
Cod. 5126 - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126* - VACUTAINER TEST TUBES CAPS PE FOR TT Ø 16 MM YELLOW
Cod. 5126.01 - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.01* - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.02 - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.02* - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.03 - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.03* - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.04 - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.04* - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.05 - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.05* - External caps for vacuum test tubes Ø15-16 mm, in PE,
Cod. 5126.XX - Caps for closure vacuum tube Ø15-16mm
Cod. 5126.XX* - Caps for closure vacuum tube Ø15-16mm
Cod. 5127 - Caps for reclosing vacuum test tubes Ø16 mm, in PE
Cod. 5129 - Caps for reclosing vacuum test tubes Ø13 mm, in PE
Cod. 5140 - 20ml cylindrical test tubes in PS, not graduated, without
Cod. 5140/E - 20ml cylindrical test tubes in PS, not graduated, without
Cod. 5140/MO - 20ml cylindrical test tubes in PP, not graduated, without
Cod. 5140/MO/E - 20ml cylindrical test tubes in PP, not graduated, without
Cod. 5140/MO/T - 20ml cylindrical test tubes in PP, not graduated, without
Cod. 5140/MO/T/SG - 20ml cylindrical test tubes in PP, without rim, with cap,
Cod. 5140/MO/TE - 20ml cylindrical test tubes in PP, not graduated, without
Cod. 5140/MO/TE/SG - 20ml cylindrical test tubes in PP, without rim, with cap
Cod. 5140/SG - 20ml cylindrical test tubes in PS. not graduated. without
Cod. 5140/T - 20ml cylindrical test tubes in PS, not graduated, without
Cod. 5140/T/SG - 20ml cylindrical test tubes in PS, without rim, with cap,
Cod. 5140/T/SG/CS - 20ml cylindrical test tubes in PS, with cap, without rim,
Cod. 5140/TE - 20ml cylindrical test tubes in PS, not graduated, without
Cod. 5140/TE/SG - 20ml cylindrical test tubes in PS, without rim, with cap
Cod. 5140/TE/SG/CS - 20ml cylindrical test tubes PS with cap & label, without rim,
Cod. 5140MO/E - 20ml cylindrical test tubes in PP, label
Cod. 5155 - Rods for clot detachment and extraction in PS, lenght 157mm
Cod. 5200/SG - L-Shape spreaders in PP, colour white, sterile
Cod. 5200/SG/CS - L-Shape spreaders in PP, colour white,
Cod. 5201/SG - L-Shape spreaders in PP, colour blue, sterile
Cod. 5201/SG/CS - L-Shape spreaders in PP, colour blue,
Cod. 5202/C - Tips in kit Eppendorf type, 0.5-10 ul cristall, neutral,
Cod. 5202/E - Tips in kit Eppendorf type, vol. 5-200 ul, yellow colour,
Cod. 5202/G - Tips in kit Gilson type, vol. 5-200 ul, yellow colour,
Cod. 5202/MG - Tips in kit Gilson type, vol. 0.1-10ul, neutral colour,
Cod. 5202/U - Tips in kit Universal type, vol. 2-200 ul, yellow colour,
Cod. 5205/SG - T-Shape spreaders in PS, colour blue, sterile R,
Cod. 5205/SG/CS - T-Shape spreaders in PS, colour blue, sterile R,
Cod. 5250 - 25ml cylindrical test tubes in PS, graduated, with rim,
Cod. 5250/MO - 25ml cylindrical test tubes in PP, graduated, with rim,
Cod. 5300 - Stirring rods in PS, Ø3 x 120 mm
Cod. 5302/G - Tips in kit Gilson type, vol. 2-200 ul, neutral colour,
Cod. 5331 - 10ml conical urine test tubes for instruments, in PS,
Cod. 5331/S - 10ml conical urine test tubes for instruments, in PS,
Cod. 5331/ST - 10ml conical urine test tubes for instruments, in PS,
Cod. 5331/TE - 10ml conical urine test tubes for instruments, in PS,

Cod. 5331/TE/SG - 10ml conical urine test tubes for instruments, PS, Ø16x105mm
Cod. 5402/B - Kit tips Biohit type 2-300ul, neutral colour
Cod. 5402/E - Tips in kit Eppendorf type, vol. 2-20 ul, neutral colour,
Cod. 5402/G - Tips in kit Gilson type, vol. 2-200 ul, yellow colour,
Cod. 5402/MG - Tips in kit Gilson type, 0.1-10ul lengthened, neutral,
Cod. 5420 - Reduction cups for Ø13mm vacuum test tubes, 1ml, in PS,
Cod. 5430 - Reduction cups for Ø16mm vacuum test tubes, 2ml, in PS,
Cod. 5434 - Square containers 2,000ml for 24h urine collection, PE,
Cod. 5434/M - Square containers 2000ml for 24h urine collection, PE,
Cod. 5471 - Bottle 24h urine collection PE ergonomic 2000ml screw cap for
Cod. 5472 - Bottle 24h urine collection PE brown 2000ml, screw cap for
Cod. 5520 - Caogulometer sample cups for Dade/Sismex CA50/500/5000 type
Cod. 5540 - Sysmex CS 2000 coagulometer cuvettes, in PS
Cod. 5555 - 10ml cylindrical test tubes in PMMA, not graduated, with
Cod. 5555/E - 10ml cylindrical test tubes in PMMA, not graduated, with
Cod. 5555/T - 10ml cylindrical test tubes in PMMA, not graduated, with
Cod. 5555/TE - 10ml cylindrical test tubes in PMMA, not graduated, with
Cod. 5558 - 5ml cylindrical test tubes in PMMA, graduated, with rim,
Cod. 5558/E - 5ml cylindrical test tubes in PMMA, graduated, with rim,
Cod. 5558/T - 5ml cylindrical test tubes in PMMA, graduated, with rim,
Cod. 5558/TE - 5ml cylindrical test tubes in PMMA, graduated, with rim,
Cod. 5575 - 5ml cylindrical test tubes in PMMA, graduated at 3ml,
Cod. 5575/E - 5ml cylindrical test tubes in PMMA, graduated at 3ml,
Cod. 560 - Microscope slides 26x76 mm, cut type, thick 1,0/1.2 mm
Cod. 561 - Microscope slides 26x76 mm, ground edges, thick 1,0/1.2 mm
Cod. 562 - Microscope slides 26x76 mm, ground edges with frosted end,
Cod. 5630 - Cuvettes in PMMA for CibaCorning Express 550 & Plus
Cod. 5640 - Ciba Corning Express 550 and Plus sample cups, 1 ml
Cod. 5650 - Ciba Corning Express 550 and Plus sample cups, 0,8 ml
Cod. 5671 - Bottle 24h urine collection PE 2000ml screw cap x vacuum test
Cod. 5672 - Bottle brown 24h urine, in PE, 2000ml screw cap x vacuum test
Cod. 5685 - Flexi-Strip for blood smear in PS, lenght 76 mm,
Cod. 5701 - Disposable forceps in ABS, ergonomic grip, lenght 124mm
Cod. 5701/CS/100 - Disposable forceps in ABS with ergonomic grip, lenght 124mm,
Cod. 5701/CS100 - Disposable forceps in ABS, ind wrapped
Cod. 5701/P - Disposable forceps in ABS
Cod. 5701/S - Disposable forceps in ABS, ergonomic grip, lenght 124mm
Cod. 5701/SG - Disposable forceps in ABS, ergonomic grip, lenght 124mm,
Cod. 5701/SG/CS - Disposable forceps in ABS, ergonomic grip, lenght 124mm,
Cod. 5701/SG/CS/100 - Disposable forceps in ABS, sterile, ind. wrapped, bags of
Cod. 5701/SG/CS/P - Disposable forceps in ABS, ergonomic grip, lenght 124mm,
Cod. 571 - Microscope coloured slides, frosted end white colour,
Cod. 572 - Microscope coloured slides, frosted end blue colour,
Cod. 573 - Microscope coloured slides, frosted end pink colour,
Cod. 5731 - Bottle 24h urine collection PE brown 3000ml, screw cap for
Cod. 5732 - Bottle 24h urine collection PE 3000ml screw cap x vacuum test
Cod. 574 - Microscope coloured slides, frosted end yellow colour,
Cod. 575 - Microscope coloured slides, frosted end green colour,
Cod. 576 - Microscope coloured slides, frosted end orange colour,
Cod. 5821 - Cuvettes for Olli-C Analyzer, 4ml, in PS, Ø12 x 50 mm
Cod. 5830 - Technicon sample cups 1.5 ml, in PS, Ø13.90 x 24.70 mm
Cod. 5840 - Abbot Architect sample cups
Cod. 5850 - SMALL SERUM CONES FOR POLIMAK IN PE - STRIPS OF 20 PCS
Cod. 5860 - AXsYM sample cups, in PS, Ø17.50 x 53 mm
Cod. 5860 - AXsYM sample cups, in PS, Ø17.50 x 53 mm
Cod. 5870 - Kodak sample cups 0.5ml in PS, Ø16 x 20 mm
Cod. 5880 - STAGO® STart® coagulation analyzer sample cups
Cod. 5890 - SIGMA® AMELUNG® KC4 DELTA™ coagulation analyzer cuvettes
Cod. 5901 - Hitachi sample cups 3ml in PS, Ø17 x 38 mm
Cod. 5903 - Hitachi sample cups, for pediatric use, Ø17 x 37 mm
Cod. 5907 - Olympus AU400/AU640 sample cups
Cod. 5907 - Olympus AU400/AU640 sample cups
Cod. 5910 - Cuvettes for ABA-VP 0.5 ml, in PS
Cod. 5920 - Cuvettes for ELVI type coagulometers, PS, 1ml
Cod. 5921 - Cuvettes for Elvi 818-819-820, 1 ml, in PS, Ø12 x 34.50 mm
Cod. 5930 - Cuvettes for Fibrintimer, 1.3ml, in PS, Ø11.9x34.5 mm,
Cod. 5931 - Option Behnk Thrombotimer cuvettes, with mixers
Cod. 5931/S - Option Behnk Thrombotimer cuvettes, without mixers
Cod. 5940 - ERIS SAMPLE CUPS IN PS DIM. 13X28MM. VOL. 1.5ML
Cod. 5941 - Cuvettes for Amelung 1.5 ml, in PS, Ø20x23mm, without mixer
Cod. 5941/S - Cuvettes for Amelung 1.5 ml, in PS, Ø20x23mm, with metallic
Cod. 5951 - Cuvette for coagulometer TECO® -DiaMed®-DIALAB® type, in PS,
Cod. 5961 - Cuvette for coagulometer TECO® -DiaMed®-DIALAB® type, in PS,
Cod. 5971 - Accu CoaData cuvettes
Cod. 5975/E - 4ml test tubes with separating granules, in PMMA, with green
Cod. 5976/E - 5ml test tubes with separating granules, in PP with green cap
Cod. 5978/E - 5ml test tubes in PP with separating granules with green
Cod. 5984 - Seac Clot S2 cuvettes

Cod. 5990 - Separating granules in PS, in packages of 1 Kg
Cod. 5993/E - 6ml test tube with separating granules, in PP, with green
Cod. 5995/E - 10ml test tube with separating granules, in PMMA, with green
Cod. 5995/ER - 10ml test tube with separating granules, in PMMA, with red
Cod. 5996/E - 10ml test tube with separating granules, in PP, with green
Cod. 5998/E - 5ml test tubes with separating granules, in PMMA, with green
Cod. 6001/F - Macro tips Finnpipette type, vol. 500-5,000 ul, neutral,
Cod. 6001/O - Macro tips Gilson type, vol. 1,000-5,000 ul, blue,
Cod. 6001/ON - Macro tips Eppendorf type, vol. 1,000-5,000 ul, neutral,
Cod. 6001/ON/SG - STER.PIPETTE TIPS RACK W/LID NEUTRAL1000-5000 UL EPPENDORF-
Cod. 6001/SG - Sterile loops 1ul, in PS, with incorporated needle,
Cod. 6001/SG/BRAND - Sterile loops 1ul, in PS, with incorporated needle, in
Cod. 6001/SG/CS - STERILE INOCULATING LOOPS 1 UL, NEUTRAL, INDIVIDUALLY
Cod. 6002/SG - Sterile loops 1ul, in PS, with incorporated needle,
Cod. 6002/SG/BRAND - Sterile loops 1ul, neutral colour, sterile in bags of 5 pcs
Cod. 6005 - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 6005/250 - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 6005/C - 10ml conical test tubes in PS, graduated, with rim, Ø16x105mm
Cod. 6005/C/50 - 10ml conical test tubes in PS, graduated, with rim, Ø16x100mm
Cod. 6005/C/500 - 10ml conical test tubes in PS, graduated, with rim, Ø16x100mm
Cod. 6005/C/T - 10ml conical test tubes in PS, graduated, with rim, Ø16x100mm
Cod. 6005/MO - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 6005/MO/250 - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 6005/MO+1127 - 10ml cylindrical test tubes in PP, Ø16x100 mm + cap with tongue
Cod. 6005/MOC - 10ml conical test tubes in PP, graduated, with rim, Ø16x105mm
Cod. 6005/SG - Sterile loops with two loops 10ul + 1 ul, in PS, yellow,
Cod. 6005/SG/100 - 10ml cylindrical test tubes PS, rim, graduated, Ø16x100mm,
Cod. 6005/SG/BRAND - Sterile loops with two loops 10ul + 1 ul, in PS, yellow,
Cod. 6005/SG/CS - Sterile loops with two loops 10ul + 1 ul, in PS, yellow,
Cod. 6009/C/E - 10ml conical test tubes in PP, with rim and label, graduated,
Cod. 6009/C/T - 10ml conical test tubes in PS, with rim and cap, graduated,
Cod. 6009/C/TR/E - 10ml conical test tubes in PS, label, red cap
Cod. 6009/E - 10ml cylindrical test tubes in PS, with rim, graduated,
Cod. 6009/MO/E - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 6009/MO/T - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 6009/MO/TB/E - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 6009/MO/TE - 10ml cylindrical test tubes in PP, with rim, graduated,
Cod. 6009/MOC/E - 10ml conical test tubes in PP, with rim and label, graduated,
Cod. 6009/T - 10 mlo cylindrical test tubes in PS, cap
Cod. 6009/T/SG/CS - 11 mlo cylindrical test tubes in PS, cap, sterile ind wrapped
Cod. 6010/SG - Sterile loops 10ul, in PS, with incorporated needle,
Cod. 6010/SG/BRAND - Sterile loops 10ul, in PS, with incorporated needle, in
Cod. 6010/SG/CS - STERILE INOCULATING LOOPS 10 UL- BLUE, INDIVIDUALLY
Cod. 6011/SG - Sterile loops 10ul, in PS, with incorporated needle,
Cod. 6011/SG/BRAND - Sterile loops 10ul, blue colour, sterile in bags of 5 pcs
Cod. 6013 - 7ml cylindrical test tubes in PS, without rim, not graduated
Cod. 6013/MO - 7ml cylindrical test tubes in PP, without rim, not graduated
Cod. 6013/SG - Sterile 7ml cylindrical tubes PS. without rim and graduation
Cod. 6013/SG/CS - 7ml cylindrical test tubes in PS, without rim, not graduated
Cod. 6013/T/SG - 7ml cylindrical test tubes in PS, without rim, not graduated
Cod. 6015/SG - Sterile loops 1+10ul, yellow colour, sterile in bags of 5 pcs
Cod. 6015/SG/BRAND - Sterile loops 1+10ul, yellow colour, sterile in bags of 5 pcs
Cod. 6040/SG - Sterile inoculation loops with needle + spreading sphere,
Cod. 61 - Petri dishes Ø 60 mm, without triple vents, in PS,
Cod. 61/N - Petri dishes Ø 60 mm, without triple vents, in PS,
Cod. 6301 - 2ml cryotubes in PP internal thread, not serigraphed,
Cod. 6302 - 1.2ml cryotubes in PP, internal thread, serigraphed,
Cod. 6311 - 2ml cryotubes in PP, internal thread, serigraphed,
Cod. 6311/R - 2ml cryotubes in PP, internal thread, cylindrical bottom,
Cod. 6321 - 4ml cryotubes in PP, internal thread, serigraphed,
Cod. 6321/R - 4ml cryotubes in PP, internal thread, cylindrical bottom,
Cod. 6331 - 5ml cryotubes in PP, skirted, internal thread, serigraphed,
Cod. 6331/R - 5ml cryotubes PP, round bottom internal thread, serigraphed,
Cod. 6402 - 1.2ml cryotubes in PP, external thread, serigraphed,
Cod. 6405 - 3ml cryotubes in PP, external thread, serigraphed,
Cod. 6411 - 2ml cryotubes in PP, external thread, serigraphed,
Cod. 6411/R - 2ml cryotubes in PP, external thread, cylindrical bottom,
Cod. 6421 - 4ml cryotubes in PP, external thread, cylindrical bottom,
Cod. 6431 - 5ml cryotubes in PP, external thread, serigraphed,
Cod. 65351 - 50ml conical test tube PP with cap, graduated serigraphed,
Cod. 65351/SG - 50ml conical test tube PP with cap, graduated serigraphed,
Cod. 65352 - 15ml conical test tube PP with cap, graduated serigraphed,
Cod. 65352/SG - 15ml conical test tube PP with cap, graduated serigraphed,
Cod. 66001 - Macro tips Gilson type, vol. 2,000-10,000ul, neutral,
Cod. 66005 - Macro tips Biohit type, vol. 2,000-10,000ul, neutral,
Cod. 6840 - Test tubes rack hermetic lid for n°40 tubes Ø12-16 mm,

Cod. 70461/SG - 50ml conical test tubes in PP for light-sensitive materials,
Cod. 70461/SG/CS - 50ml conical test tubes in PP for light-sensitive materials,
Cod. 70462/SG - 15ml conical test tubes in PP, for light-sensitive materials,
Cod. 70462/SG/CS - 15ml conical test tubes in PP, for light-sensitive materials,
Cod. 80461/SG - 50ml conical tube PP with base for light-sensitive materials
Cod. 80461/SG/CS - 50ml conical tube PP with base for light-sensitive materials,
Cod. 81 - Petri dishes Ø 80 mm, without triple vents, in PS,
Cod. 81/N - Petri dishes in PS Ø80mm, without vents, no sterile
Cod. 91 - Petri dishes Ø 90 mm, with triple vents, in PS
Cod. 91/AN - Petri dishes Ø 90 mm, with triple vents, in PS
Cod. 91/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 91/SAC - Petri dishes Ø 90 mm, with triple vents, in PS
Cod. 91/SG - Petri dishes Ø 90 mm, with triple vents, in PS
Cod. 91/SG/AN - Petri dishes Ø 90 mm, with triple vents, in PS
Cod. 91/SG/B - Petri dishes Ø 90 mm, with triple vents, in PS,
Cod. 91/SG/SAC - Petri dishes in PS Ø90mm, with vents, sterile
Cod. 9402 - Filter tips for Biohit m-Line/Proline Plus, 0,1-10ul, neutral, rack
Cod. 9501 - Filter tips Eppendorf type, vol. 101-1000 ul, neutral,
Cod. 9501/NS - FILTER TIPS EPPENDORF NEUTRAL 101-1001 UL - BAGS OF 1000 PCS
Cod. 9501/S - Filter tips Eppendorf type, vol. 101-1000 ul, neutral,
Cod. 9502 - Filter tips Eppendorf type, vol. 5-100 ul, neutral,
Cod. 9503 - Filter tips Eppendorf type, vol. 0.5-10 ul, neutral,
Cod. 9503/NS - FILTER TIPS EPPENDORF CRISTALL NEUTR. 0,5-10 UL BAGS OF 1000
Cod. 9503/S - STERILE FILTER TIPS 0,5-10 UL NEUTRAL EPP.CRISTALL BAGS 1000
Cod. 9504 - Filter tips Eppendorf type, vol. 2-20 ul, neutral colour,
Cod. 9504/NS - FILTER TIPS EPPENDORF NEUTRAL 2-20UL - BAGS OF 1000 PCS
Cod. 9504/S - STER. FILTER TIPS 2-20 UL EPPE NDORF NEUTRAL - BAGS 1000 PCS
Cod. 9601 - Filter tips Gilson type, 2-160ul beveled grad, neutral,

Cod. 9603 - Filter tips Gilson type, 2-100ul beveled grad, neutral,
Cod. 9605 - Filter tips Gilson type, 2-30ul beveled gradu, neutral,
Cod. 9606 - Filter tips Gilson type, vol. 2-200ul beveled, neutral,
Cod. 9610 - Filter tips Gilson type, vol. 0.1-10 ul, neutral,
Cod. 9615 - Filter tips Gilson type, vol. 101-1000 ul, neutral,
Cod. 9620 - Filter tips Eppendorf type, 20-300 ul graduated, neutral,
Cod. 9620/NS - FILTER TIPS EPPENDORF UNIVERS. NEUTRAL 20-300UL BAGS 1000 PCS
Cod. 9620/S - STER. FILTER TIPS UNIVERSAL NEUTRAL 20-300UL - BAGS 1000
Cod. 9701 - Filter tips Universla type, vol. 100-1000 ul, neutral,
Cod. 9702 - Tips for gel loading in PP, vol. 0.1-200 ul, neutral,
Cod. 9703 - Filter tips Universla type, vol. 50-1000 ul, graduated,
Cod. 9710 - Filter tips Gilson type, vol. 0.1-10 ul, neutral,
Cod. 9711 - Filter tips Universal type, vol. 2-200 ul, neutral,
Cod. 9712 - Filter tips universal type in PP, vol. 2-30 ul, neutral,
Cod. 9713 - Filter tips universal type in PP, vol. 2-100 ul, neutral,
Cod. 9801 - Macro tips Gilson type with filter vol. 1000-5000 ul, blue
Cod. 9802 - Macro tips Eppendorf type with filter vol. 1000-5000 ul,
Cod. 9803 - Macro tips Finnpipette type with filter, vol. 1000-5000ul,
Cod. 9810 - Macro tips Gilson type with filter, vol. 2000-10000 ul,
Cod. 9811 - Macro tips Biohit type with filter, vol. 2000-10000 ul,
Cod. 9901/B - GreenTip neutral tips 0.1-10ul, universal type, in rack
Cod. 9902/B - GreenTip neutral tips 2-100ul, universal type, in rack
Cod. 9903/B - GreenTip neutral tips 100-1000ul, universal type, in rack
Cod. 9920/B - GreenTip neutral filter tips 0,1-10ul, universal type, in rack
Cod. 9921/B - GreenTip neutral filter tips 2-100ul, universal type, in rack
Cod. 9922/B - Neutral tips 2-200ul, sterile with filter, Universal type,
Cod. 9923/B - Tip with filter universal type , vol. 100-1000 ul, in rack in
Cod. 9940009146 - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. 9949009146 - Graduated urine container with screw cap, PP, 58x72, 150ml
Cod. S10110/PR - Test tubes Ø12x86mm in PP, with 0,2ml NA Citrate, for

I suddetti prodotti, in base all'art. 4 della direttiva 98/79/CE, sono di libera circolazione e possono essere messi in commercio in Italia e in tutto il territorio dell'Unione Europea.
Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione.

The above mentioned products, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union.
This certificate is issued on the interested company's request according to the law and for exporting.

IL DIRETTORE
THE DIRECTOR
Dr.ssa Paola D'Alessandro

IC/CM

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
13.02.2018

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **3771/E/TB**

DESCRIZIONE / *DESCRIPTION*

Provetta cilindrica Ø16 x 100 mm prodotta in Polipropilene medicale (PP), infrangibile, translucido ed inerte, Le provette contengono gel separatore con aggiunta, per migliorare la separazione, di granuli separatori in polistirolo (inerti, tondeggianti e privi di asperità al fine di evitare la rottura delle cellule durante la centrifugazione) per 10,0 ml di sangue i quali formano una sufficiente barriera ermetica tra plasma e siero in seguito alla centrifugazione (raccomandiamo di non superare RCF 1.500 x g). Corredate di etichetta autoadesiva applicata e tappo a pressione in polietilene (PE) di colore rosso a presa bassa a perfetta tenuta. Centrifugabili a max 5.000 RPM. Dispositivo latex free

Cylindrical test tube Ø16 x 100 mm in medical Polypropylene (PP), unbreakable, translucent and inert Test tubes contain separating silicone gel and, for a better use, PS separating granules (inert and smoothly rounded to avoid cells breakage during centrifugation) for 10.0 ml of blood, forming a hermetic barrier between plasma and serum following to centrifugation (it is recommended not to centrifuge at more than RCF 1,500 x g). Supplied with applied label and polyethylene (PE) cap, red colour, low grip, perfectly tight. The test tubes can be centrifuged at max 5,000 RPM. Latex free device

Prodotto con marchio CE - conforme alla Direttiva 98/79/CE e al D.lgs 332 del 08/09/2000

CE Marked product - manufactered in compliance with 98/79/CE Directive and D.lgs 332 dtd 08/09/2000

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbilogical status*
Materiale impiegato provetta	POLIPROPILENE / *POLYPROYILENE*	*Raw material – test tube*
Materiale impiegato tappo	POLIETILENE / *POLYETHYLENE*	*Raw material – cap*
Temperature tollerate provetta	MIN -10°C MAX +121°C	*Temperature range - test tube*
Temperature tollerate tappo	MIN -50°C MAX +75°C	*Temperature range - cap*
Volume nominale (ml)	10 ML	*Nominal volume (ml)*
Dimensioni provetta (mm)	Ø 16 X 100 MM	*Dimensions – test tube (mm)*
Validità del prodotto	2 ANNI / *YEARS*	*Shelf life*

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DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione d'uso è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (sangue) al fine di effettuare analisi diagnostiche di laboratorio.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale dei Dispositivi Medici (CND) > W050101010201 (Provette con additivi o separatori di siero per raccolta di sangue)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1246044/R
Classificazione EDMA: 51011001 - Tubes for serum (without anticoagulant)

The intended purpose is "IN VITRO DIAGNOSTIC MEDICAL DEVICE" able to contain a human biological sample (blood) and in order to carry out analysis of laboratory diagnosis. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > *W050101010201 (Blood collection, tubes with additives or serum separator)*
EDMA code: *51011001 - Tubes for serum (without anticoagulant)*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, lontano da fonti di calore e non esporre alla luce diretta del sole.
Store in dry place, far away from heat sources and not to expose to the direct light of the sun.

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	1.000	Confezione interna (pz): *Internal packing (pcs):*	50 pezzi in rack polistirolo espanso *50 pieces in styrofoam racks*	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*			
Misura esterna scatola (cm): *External box dimensions (cm):*	56 x 23,5 x 43	Peso (Kg): *Weight (Kg):*	9,0	Volume (m^3): *Volume (m^3):*	0,056		

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable