By Royal Charter

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Effective Date: 2024-04-14
Latest Revision Date: 2024-03-26
Expiry Date: 2027-04-13

Digitally signed by Ceaicovschi Tudor
Date: 2026.04.22 15:02:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

...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

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Declaration of Conformity

HL-7-0135DC DOI 2015/07 (7)

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: 28 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
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Declaration of Conformity

HL-7-0137DC DOI 2015/07 (7)

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: 28 Jul 2015

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Declaration of Conformity

HL-7-0138DC DOI 2015/07 (7)

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: 28 Jul 2015

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Declaration of Conformity

HL-7-0511DC DOI 2015/08 (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
5376	Clauss Fibrinogen 100	55997

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: 12 Aug 2015

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Declaration of Conformity

HL-7-0660DC 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
5267	Thromboplastin LI	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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Medica Corporation
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Products For Health Care

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
EasyElectrolyte and accessories per attachment	EasyElectrolyte Na/K/Cl, Na/K/Li
EasyStat and accessories per attachment	pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct
EasyBloodGas and accessories per attachment	pH/pCO2/pO2

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Molenstraat 15
NL-2513 BH The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are in conformity with the Annex III, essential requirements and provisions of council Directive: 98/79/EC

Place and Date: Bedford, Massachusetts, USA, March 1, 2012

Signature:

Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 10
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution Kit	11 01 01 27
6402	Red Test Dye Solution	11 70 31 90
6503	EasyBloodGas Capillary Tube Kit	21 04 10 01
6603	EasyBloodGas Demonstration Kit	21 04 10 01
6306	EasyBloodGas Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
6506	EasyBloodGas Sensor Module	21 04 10 01
6507	EasyStat/EasyBloodGas Valve Module	21 04 10 01
6508	Compression Plate	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 04 10 01
7309	Bi-Level Hematocrit Quality Control	13 01 70 03
7603	EasyStat Demonstration Kit	21 04 10 01
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 04 10 01
7306	EasyStat Sampler	21 04 10 01
7304	EasyStat Pump Tube	21 04 10 01
7506	EasyStat Sensor Module	21 04 10 01
7302	Probe Wipers	21 04 10 01

EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 03 01
4103	EasyElectrolyte Reagent Module Na/K/Li	11 03 01
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	Red Test Dye Solution	11 70 31 90
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 04 10 01
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	21 04 10 01
4404	EasyElectrolyte Capillary Tube Kit	21 04 10 01
4306	EasyElectrolyte Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
4506	EasyElectrolyte Sensor Module	21 04 10 01
4507	EasyElectrolyte Valve Module	21 04 10 01
4508	Compression Plate	21 04 10 01
7302	Probe Wipers	21 04 10 01
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 04 10 01
4539	EasyElectrolyte Sensor Module, Li	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
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 Refrence Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
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 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 04 10 01
2108	EasyLyte Solutions Valve	21 04 10 01
2107	EasyLyte Sample Probe	21 04 10 01
2257	EasyLyte Sample Detector	21 04 10 01
2104	EasyLyte Tubing Kit	21 04 10 01
2100	EasyLyte Calcium Tubing Kit	21 04 10 01
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 04 10 01
2541	EasyLyte Printer Paper (3 rolls)	21 04 10 01

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 04 10 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 04 10 01
10745	Anti-Evaporation Caps (500)	21 04 10 01
2293	EasyLyte Capillary Tubes	21 04 10 01
2590	EasyLyte Capillary Adaptor Kit	21 04 10 01
2292	EasyLyte Capillary Adaptor Cleaning Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 04 04 90
2572	EasyLyte Troubleshooting Kit	21 04 10 01
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 04 10 01
2105	EasyLyte Quarterly Operating Kit	21 04 10 01
2095	EasyLyte Maintenace Kit	21 04 10 01
2076	EasyLyte Sample Tray	21 04 10 01
2074	EasyLyte Sample Cup Retainer Ring	21 04 10 01
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 04 10 01

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Declaration of Conformity CE

Product Name:

EasyLyte Analyzer and accessories per attachment

Model/Type:

Na/K, Na/K/Cl, Na/K/Li,
Na/K/Cl/Li, Na/K/Ca/pH,
Na/K/Cl/Ca/Li

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA
Single Registration Number (SRN): US-MF-000037250

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

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 their corresponding amendments.

Place and Date: Bedford, Massachusetts, USA, 26 May 2022

Signature:

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

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Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2004	EasyLyte Analyzer, Na/K	21 07 11 02	General IVD device, not listed in IVDD Annex II and not intended for self-testing
2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
2021	EasyLyte Analyzer, Na/K/Cl/Li	21 07 11 02	
2030	EasyLyte Analyzer, Na/K/Cl/Ca/Li	21 07 11 02	
C2004	EasyLyte Analyzer, Na/K	21 07 11 02	
C2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
C2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
C2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
C2030	EasyLyte Analyzer, Na/K/Cl/Ca/Li	21 07 11 02	
L2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
L2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
L2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
L2021	EasyLyte Analyzer, Na/K/Cl/Li	21 07 11 02	
2101	EasyLyte K+ Electrode	11 04 01 06	
2102	EasyLyte Na+ Electrode	11 04 01 07	
2103	EasyLyte Reference Electrode	11 04 04 01	
2113	EasyLyte Cl- Electrode	11 04 01 03	
2106	EasyLyte Lithium 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	
2109	EasyLyte Solutions Pack, 400mL	11 04 04 02	
2120	EasyLyte Solutions Pack, 800mL	11 04 04 02	
2112	EasyLyte Plus Solutions Pack, 400mL	11 04 04 02	
2121	EasyLyte Plus Solutions Pack, 800mL	11 04 04 02	
2115	EasyLyte Lithium Solutions Pack, 400mL	11 04 04 02	
2122	EasyLyte Lithium Solutions Pack, 800mL	11 04 04 02	
2114	EasyLyte Calcium Solutions Pack, 400mL	11 04 04 02	
2123	EasyLyte Calcium Solutions Pack, 800mL	11 04 04 02	
2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL	11 04 04 02	
2028	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL	11 04 04 02	
2124	EasyLyte Na/K/Cl/Ca/Li Solutions Pack, 800mL	11 04 04 02	

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Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04	General IVD device, other than listed in IVDD Annex II and other than intended for self-testing
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04	
L2026	EasyLyte Solutions Pack, Na/K/Cl/Li, 800mL	11 04 04 02	
L2112	EasyLyte Solutions Pack, Na/K/Cl, 400mL	11 04 04 02	
L2121	EasyLyte Solutions Pack, Na/K/Cl, 800mL	11 04 04 02	
L2122	EasyLyte Solutions, Na/K/Li Pack, 800mL	11 04 04 02	
L2123	EasyLyte Solutions Pack, Na/K/Ca/pH, 800mL	11 04 04 02	

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Declaration of Conformity CE

Product Name:

EasyLyte consumables and accessories per attachment

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA
Single Registration Number (SRN): US-MF-000037250

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Single Registration Number (SRN): NL-AR-000000116
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Means of Conformity

Medica Corporation declares that the Class A products listed are in conformity with the provisions of Regulation (EU) 2017/746 In Vitro Diagnostic Medical Devices. These products are classified as class A IVDR devices based on Rule 5, ANNEX VIII Regulation (EU) 2017/746. In addition, they are in conformity with the Annex I, “General Safety and Performance Requirements” and provisions of regulation of (EU) 2017/746 for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, REACH (1907/2006EC), 1272/2008/EC CLP and the corresponding national laws of the Member States.

Medica Corporation is solely responsible for the contents of this document.

Place and Date: Bedford, Massachusetts, USA, 26 May 2022
Signature:

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

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List of Consumables and Accessories

Catalog No.	Products	EDMA Code	Intended Use	Basic UDI	Class
2070	EasyLyte Easysampler	21 07 11 02	Used for automated batch sampling of serum, plasma or diluted urine on the analyzer	0379497ELNAKCL26	A
2095	EasyLyte Maintenance Kit	21 07 11 02	Used to perform routine maintenance on the EasyLyte analyzers	0379497ELNAKCLCALIQZ	A
2100	EasyLyte Calcium Tubing Kit	21 07 11 02	Used to move patient sample from the probe to the electrode stack for sample analysis on the analyzer	0379497ELNAKCAPHJM	A
2104	EasyLyte Tubing Kit	21 07 11 02	Used to move patient sample from the probe to the electrode stack for sample analysis on the analyzer	0379497ELNAKCLCALIQZ	A
2105	EasyLyte Quarterly Operating Kit	21 07 11 02	Used to perform quarterly maintenance on the analyzer	0379497ELNAKCLCALIQZ	A
2107	EasyLyte Sample Probe	21 07 11 02	Used to aspirate samples for patient analysis	0379497ELNAKCL26	A
2108	EasyLyte Solutions Valve	21 07 11 02	Used to retrieve solutions from the EasyLyte analyzer solution packs	0379497ELNAKCL26	A
2111	EasyLyte Urine Diluent, 500 mL	11 04 04 90	Used to dilute urine samples in patient analysis	0379497ELNAKCLCALIQZ	A
2118	EasyLyte/EasyStat/EasyBloodGas /EasyElectrolytes Daily Rinse/ Cleaning Solution Kit	11 01 01 27	Used to remove protein deposits that have built up on the electrodes in the flow path	0379497ELNAKCLCALIQZ	A
2257	EasyLyte Sample Detector	21 07 11 02	Used during the analysis of patient samples	0379497ELNAKCL26	A
2258	EasyLyte Membrane Assembly	21 07 11 02	Used during patient sample analysis on the EasyLyte analyzer	0379497ELNAKCL26	A
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02	Used to analyze patient samples in capillary mode on the EasyLyte analyzers	0379497ELNAKCL26	A
2293	EasyLyte Capillary Tubes	21 07 11 02	Used to analyze patient samples in capillary mode	0379497ELNAKCLCALIQZ	A
2309	EasyLyte Wash Solution, 50mL	11 04 04 90	Used to clean the electrode flow path on the analyzer	0379497ELNAKCLCALIQZ	A
2323	EasyLyte Probe Wipers	21 07 11 02	Used to remove excess sample material from the probe	0379497ELNAKCL26	A
2492	EasyLyte Internal Filling Solution	11 04 04 90	Used to fill the electrode housing on the Na/K, Na/K/Cl and Na/K/Li analyzer	0379497ELNAKCL26	A
2541	EasyLyte Printer Paper	21 07 11 02	Used to print sample results performed on the analyzer	0379497ELNAKCLCALIQZ	A
2544	EasyLyte C Series Printer Paper	21 07 11 02	Used to print sample results performed on the analyzer	0379497ELNAKCLCALIQZ	A
2571	EasyLyte Troubleshooting Kit	21 07 11 02	Used to troubleshoot the Na/K/Cl/Ca/pH analyzers	0379497ELNAKCLCALIQZ	A
2572	EasyLyte Troubleshooting Kit	21 07 11 02	Used to troubleshoot the analyzer	0379497ELNAKCLCALIQZ	A
2577	EasyLyte Standard Solution, Urine	11 04 04 90	Used to analyze the performance of the EasyLyte analyzer in urine mode	0379497ELNAKCLCALIQZ	A
2578	EasyLyte Red Dye Test Solution	11 30 01 11	Used to troubleshoot fluid flows issues on the EasyLyte Analyzer	0379497ELNAKCLCALIQZ	A
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02	Used to perform a cleaning cycle in capillary mode	0379497ELNAKCL26	A
2595	EasyLyte EasySampler Sample Cups	21 07 11 02	Used to hold patient samples	0379497ELNAKCL26	A

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Catalog No.	Products	EDMA Code	Intended Use	Basic UDI	Class
2596	EasyLyte Sample Cup	21 07 11 02	Used to hold patient samples	0379497ELNAKCLCALIQZ	A
2598	EasyLyte Daily Cleaner Cup	21 07 11 02	Used to hold daily cleaning solution when using the EasySampler	0379497ELNAKCLCALIQZ	A
2843	EasyLyte QC Sample Cups	21 07 11 02	Used to hold patient samples	0379497ELNAKCLCALIQZ	A
2934	EasyLyte Barcode Reader Kit	21 07 11 02	Used to read the barcodes	0379497ELNAKCLCALIQZ	A
7118	EasyLyte Calcium/EasyLyte Expand Daily Rinse/Cleaning Solution Kit	11 01 01 27	Used to remove protein deposits from the fluid and sensor paths on the Ca/pH analyzer.	0379497ELNAKCLCALIQZ	A

References of common specifications and/or technical standards applied for this declaration of conformity, or parts thereof:

No.	Title
EN ISO 13485:2016 EN ISO 13485:2016+AC2018	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 15223-1:2021	Symbols to be used with medical devices labels
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2019	Application of risk management to medical devices
EN 23640:2011	Stability testing of in vitro diagnostic reagents
EN ISO EC17050-1: 2004	Conformity assessment. Supplier's declaration of conformity.
EN ISO 18113-2: 2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 2: In vitro diagnostic reagents for professional use.

RUSSIAN FEDERATION

№ 0228552

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.60057

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС40
Общество с ограниченной ответственностью "Прогресс"
Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,
ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

ВЫДАН
Общество с ограниченной ответственностью «Агат-Мед»
ИНН: 7719187311 ОГРН: 1037739078970
Адрес: Россия, 105173, г. Москва, ул. Главная, д. 6, кв. 12.
Фактический адрес: 143906, Московская область, г. Балашиха, квартал Щитниково, д. 88А

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА

Применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС40.60057П от 03.09.2024

Проверка подлинности сертификата соответствия

Руководитель органа _____ (подпись) Е.К. Яшин (инициалы, фамилия)

Эксперт _____ (подпись) П.К. Чеснокова (инициалы, фамилия)

Сертификат не применяется при обязательной сертификации

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АО «ОПЦИОН», Москва, 2024 г., «Б». ТЗ № 312.

RUSSIAN FEDERATION

№ 0228553

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ПромТех Стандарт

ИСО

РАЗРЕШЕНИЕ

НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.60057Р

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,

ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

ВЫДАНО

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Фактический адрес: 143906, Московская область, г. Балашиха, квартал Щитниково, д. 88А

на основании сертификата соответствия № **РОСС RU.32001.04ИБФ1.ОС40.60057**

Настоящее разрешение предоставляет право применения знака соответствия системы добровольной сертификации «ПРОМТЕХСТАНДАРТ»:

при маркировке продукции, при оказании работ (услуг), на бланках организации, в рекламно-информационных материалах, печатных изданиях, вывесках, выставочных стендах и т.д., на сайтах организации в сети Интернет, в соответствии с правилами применения знака соответствия системы добровольной сертификации "ПромТехСтандарт"

ПРОГРЕСС

Руководитель органа _____ (подпись) Е.К. Яшин (инициалы, фамилия)

Эксперт _____ (подпись) П.К. Чеснокова (инициалы, фамилия)

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АО «ОПЦИОН», Москва, 2024 г., «В». ТЗ № 312.

RUSSIAN FEDERATION

№ 0228554

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.13294Э

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,

ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям,

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок системы менеджмента качества на соответствие

требованиям стандарта:

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,

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и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт"

Руководитель органа _____ (подпись) Е.К. Яшин (инициалы, фамилия)

Эксперт _____ (подпись) П.К. Чеснокова (инициалы, фамилия)

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АО «ОПЦИОН», Москва, 2024 г., «В», ТЗ № 312

RUSSIAN FEDERATION

№ 0228555

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ПромТех Стандарт ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.13295Э

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,

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НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям,

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок системы менеджмента качества на соответствие

требованиям стандарта:

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,

протокол № РОСС RU.32001.04ИБФ1.ОС40.13295ПЭ от 03.09.2024

и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт"

ПРОГРЕСС

Руководитель органа _____ (подпись) Е.К. Яшин (инициалы, фамилия)

Эксперт _____ (подпись) П.К. Чеснокова (инициалы, фамилия)

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АО «ОПЦИОН», Москва, 2024 г., «В», ТЗ № 312.

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
TPHA Microtitre plate kit	043100A

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.

MAREA BRITANIE

KIT DE HEMAGLUTINARE PE PLACĂ DE MICROTITRU

INSTRUCŢIUNI DE UTILIZARE

Kit placă de microtitru TPHA: Pentru determinarea calitativă a *Treponema pallidum*.

REZUMAT

Sifilisul este o boală venerică provocată de microorganismul spirochetă *Treponema pallidum.* Întrucât acest organism nu poate fi cultivat în mediul artificial, diagnosticarea sifilisului depinde de corelarea datelor clinice cu anticorpul specific demonstrat prin teste serologice. Există două tehnici diferite de detectare a sifilisului. Testele TPHA pentru detectarea anticorpilor la *Treponemal pallidum* şi testele serologice non-treponemice, pentru detectarea unei substanţe asemănătoare anticorpului la persoanele infectate numită reagină.

SCOPUL PROPUS

Acesta este un reactiv de test latex pentru determinarea calitativă şi semicantitativă a prezenţei sau absenţei anticorpilor T. pallidum în serul sau plasma pacienţilor în cazul testării conform tehnicilor recomandate şi prezentate în aceste instrucţiuni de utilizare.

PRINCIPIUL

TPHA (Testul de hemaglutinare a Treponemei Pallidum) este un test de hemaglutinare indirect pentru detectarea calitativă şi semicantitativă a anticorpilor T. Pallidum specifici în serul uman. Eritrocitele aviare stabilizate, sensibilizate cu o soluţie T. Pallidum antigenică, aglutinează în prezenţa anticorpilor T. Pallidum pentru a conferi un model caracteristic. Neaglutinarea indică, în general, absenţa anticorpilor (consultaţi **Limitări**).

DESCRIEREA KITULUI

Kitul TPHA Lorne detectează anticorpii la T. pallidum. Celulele de testare sunt eritrocite aviare conservate acoperite cu componente antigenice ale T. pallidum patogenic (tulpina Nichols). Orice reacţii nespecifice sunt detectate cu ajutorul celulelor martor; eritrocite aviare neacoperite cu antigene T. pallidum. Reacţiile nespecifice pot fi, de asemenea, eliminate prin absorbţie cu ajutorul celulelor martor. Anticorpii la treponemele nepatogenice sunt absorbiţi de un extract din treponemele Reiter în suspensia de celule. Reactivele nu conţin sau nu sunt compuse din substanţe CMR, substanţe perturbatoare pentru sistemul endocrin sau care ar putea provoca sensibilizare sau o reacţie alergică în cazul utilizatorului. Reactivii sunt furnizaţi la diluarea optimă pentru utilizare cu toate tehnicile recomandate fără să fie necesară diluarea sau adăugarea suplimentară. Pentru numărul de referinţă al lotului şi data de expirare, consultaţi **Eticheta flaconului**.

DEPOZITARE

Toate componentele kitului vor rămâne stabile până la data de expirare imprimată pe etichetă, când sunt depozitate bine închise la 2-8 ºC şi este prevenită contaminarea în timpul utilizării. A nu se congela: reactivii congelaţi ar putea modifica funcţionalitatea testului. Depozitaţi flacoanele în poziţie verticală. Depozitarea în poziţie orizontală poate provoca aglomerări de celule. În cazul modificării poziţiei, amestecaţi uşor pentru a dizolva eventualele agregate prezente.
Deteriorarea reactivilor: Prezenţa aglomerărilor, particulelor şi turbidităţii.

SPECIMENE

Ser sau plasmă proaspătă. Stabile 8 zile la 2-8 ºC sau 3 luni la –20 ºC.
Probele care prezintă fibrină trebuie centrifugate înainte de testare. Nu utilizaţi probe intens hemolizate sau lipemice.

PRECAUŢII

1. Kitul este destinat exclusiv pentru diagnosticare *in-vitro*.
2. Nu utilizaţi kitul după data de expirare (consultaţi **Eticheta de pe flacon şi de pe cutie**).
3. Purtaţi echipament de protecţie când manipulaţi reactivii, cum ar fi mănuşi de unică folosinţă şi un halat de laborator.
4. Reactivii din acest kit au fost procesaţi pentru a reduce încărcătura biologică, dar nu sunt livraţi sterili. După deschiderea flaconului, conţinutul ar trebuie să rămână viabil până la data de expirare.
5. Nu se cunosc teste care să garanteze faptul că produsele derivate din surse umane sau animale nu prezintă agenţi infecţioşi. Fiţi atenţi când utilizaţi şi când eliminaţi un flacon şi conţinutul acestuia.

ELIMINAREA REACTIVULUI DIN KIT ŞI CUM SE ACŢIONEAZĂ ÎN CAZ DE STROPIRE

Pentru informaţii privind eliminarea reactivului din kit 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 în paralel a martorilor pozitivi şi negativi TPHA cu fiecare lot de teste. Testele trebuie considerate nevalide dacă probele martor nu prezintă rezultatele prevăzute.
2. Înainte de utilizare, trebuie să aşteptaţi ca reactivii să ajungă la 18-25 ºC.
3. Evitaţi contaminarea reactivilor sau serului cu salivă, deoarece aceasta va determina rezultate fals pozitive la specimene.
4. Nu schimbaţi între ele componentele de la diferite kituri.
5. Utilizarea kitului şi interpretarea rezultatelor trebuie efectuate de personal calificat şi instruit în mod corespunzător în conformitate cu cerinţele ţării în care se utilizează kitul, iar utilizatorul trebuie să stabilească în ce măsură se poate utiliza kitul în alte tehnici.

COMPONENTELE KITULUI FURNIZATE

1) R1: Celule de testare (Capac galben, 1x7,5 ml): Eritrocite aviare stabilizate, sensibilizate cu antigene T. Pallidum *(Nichols),* conservant, pH 7,2.
2) R2: Celule martor (Capac verde, 1x7,5 ml): Suspensie stabilizată de eritrocite aviare, conservant, pH, 7,2.
3) R3: Diluant TPHA (Capac alb, 2x10 ml): Soluţie salină tampon fosfat, pH 7,2, extract *T. pallidum* (Reiter), conservant.
4) Martor + (Capac roşu, 1x1 ml): Ser uman imun prediluat 1:20, conservant.
5) Martor – (Capac albastru, 1x1 ml): Ser animal, conservant.

MATERIALE ŞI ECHIPAMENTE CARE SUNT NECESARE, DAR NU SUNT FURNIZATE

a) Pipete de precizie.
b) Plăci de microtitru cu godeuri în formă de U.

TEHNICA DE EVALUARE CALITATIVĂ

1. Aşteptaţi ca reactivii şi proba să ajungă la temperatura camerei.
2. Agitaţi uşor, însă temeinic, flacoanele cu celulele de testare şi martor chiar înainte de utilizare.
3. Diluaţi proba 1:20 cu diluant (10 µl ser + 190 µl diluant (R3)).
4. Pipetaţi în godeurile alăturate ale plăcii de microtitru:

	Godeu de testare	Godeu martor
Probă 1:20 sau martor*	25 µl	25 µl
Celule martor	--	75 µl
Celule de testare	75 µl	--

*Pentru fiecare martor pozitiv sau martor negativ ori probă de la pacient testată, este necesar câte 1 godeu de testare şi 1 godeu martor.

5. Amestecaţi bine placa de microtitru până când obţineţi o probă/celule omogenă(e).
6. Acoperiţi placa de microtitru şi incubaţi la temperatura camerei timp de 45-60 min. Ţineţi placa departe de microtitru de vibraţii, căldură şi lumina directă a soarelui.
7. Examinaţi macroscopic modelele de aglutinare a celulelor.

TEHNICA DE EVALUARE SEMICANTITATIVĂ

1. Fiecare specimen necesită 8 godeuri ale unei plăci de microtitru, etichetate de la A la H.
2. Puneţi 25 µl de diluant în godeurile B până la H inclusiv.
3. Transferaţi 25 µl din proba diluată 1:20, în cadrul **Tehnicii de evaluare calitativă** de mai sus, în godeurile A şi B.
4. Luaţi 25 µl de probă diluată din godeul B şi dublaţi diluţiile probei din godeurile B până la H inclusiv, eliminând 25 µl de probă diluată din godeul H.
5. Adăugaţi 75 µl de celule de testare în godeurile A până la H inclusiv.
6. Agitaţi uşor placa de microtitru pentru a amesteca bine conţinutul.
7. Acoperiţi placa de microtitru şi incubaţi la temperatura camerei timp de 45-60 min. Ţineţi placa de microtitru departe de vibraţii, căldură şi lumina directă a soarelui.
8. Examinaţi macroscopic modelele de aglutinare a celulelor.

INTERPRETAREA REZULTATELOR

Citiţi rezultatele comparând modelele de aglutinare a celulelor de testare cu cele ale celulelor martor. Valorile sunt evaluate şi raportate după următoarele criterii:

Grad de hemaglutinare	Valoare	Rezultat
Strat fin de celule care acoperă complet fundul godeului, uneori cu margini pliate	4+	Reactiv
Strat fin de celule care acoperă parţial fundul godeului	3+	Reactiv
Strat fin de celule înconjurat de un cerc roşu	2+	Reactiv
Strat fin de celule care acoperă o suprafaţă mai mică şi este înconjurat de un cerc roşu mai mic	1+	Reactiv
Buton de celule cu o gaură mică în mijloc	±	Borderline
Un buton definit şi compact de celule, uneori cu o gaură foarte mică în mijloc.	-	Negativ

INTERPRETAREA REZULTATELOR

1. Martorul negativ nu trebuie să prezinte niciun semn de aglutinare, nici la celulele de testare, nici la cele martor.
2. Martorul pozitiv trebuie să prezinte modele de aglutinare numai la celulele de testare.
3. Orice model de aglutinare afişat de celulele martor indică prezenţa unor anticorpi nespecifici şi nu poate fi interpretat.
4. Probele cu un model borderline (de graniţă) trebuie retestate şi raportate ca negative dacă este reprodus acelaşi model.
5. Probele reactive trebuie eliminate la titrare după cum se arată la tehnica de evaluare semicantitativă de mai sus. Titrul serului este definit drept cel mai înalt grad de diluare care prezintă un rezultat reactiv.
6. Diagnosticul clinic nu trebuie efectuat pe baza rezultatului unui singur test, ci trebuie să integreze atât date clinice, cât şi de laborator.

LIMITĂRI

1. Întrucât acest kit nu poate face distincţie între sifilis şi alte infecţii treponemale patogenice, de ex. Yaws, trebuie analizate întotdeauna dovezile clinice. Se recomandă ca toate rezultatele pozitive să fie confirmate printr-o metodă alternativă, cum ar fi FTA-ABS.
2. Kitul TPHA Syphilis Lorne are un înalt grad de specificitate, dar au fost semnalate rezultate fals pozitive la probe de la pacienţi cu mononucleoză, lepră, borelioză, boli autoimune şi toxicomanie.
3. Testul TPHA nu este util în stabilirea eficienţei terapiei, deoarece nivelul de anticorpi se păstrează (ceea ce ar indica un rezultat pozitiv la test) un anumit timp după ce bolnavul este declarat vindecat din punct de vedere clinic.
4. Rezultatele fals pozitive sau fals negative pot fi provocate şi de:
   - Contaminarea materialelor folosite în testare
   - Depozitarea necorespunzătoare a materialelor de testare sau omiterea reactivului
   - Abaterea de la tehnicile recomandate

CARACTERISTICI DE PERFORMANŢĂ SPECIFICE

1. Kitul a fost caracterizat prin procedurile menţionate în **Tehnici recomandate**.
2. Înainte de a fi pus pe piaţă, fiecare lot de TPHA Syphilis Kit Lorne este testat conform **Tehnicilor recomandate** pentru a se asigura reactivitatea adecvată.
3. Bilirubina (≤ 20 mg/dl), hemoglobina (≤ 10 g/l), lipidele (≤ 10 g/l) şi factorii reumatoizi (≤ 300 IU/ml) nu afectează rezultatele. Alte substanţe pot influenţa rezultatele[1].
4. **Sensibilitate analitică**: 0,1 IU/ml, testat conform Primului standard internaţional pentru plasma sifilizată umană IgG şi IgM, codul NIBSC 05/132.
5. **Efect de prozonă:** Nu a fost detectat niciun efect de prozonă la titre ≥1/163840.
6. **Sensibilitate diagnostic:** 100%
7. **Specificitate diagnostic:** 100%.

DECLINAREA RESPONSABILITĂŢII

1. Utilizatorul este singurul responsabil pentru performanţa reactivilor în cazul utilizării altor metode decât cele menţionate în **Tehnici recomandate**.
2. Orice abatere trebuie validată înainte de utilizare cu ajutorul procedurilor de laborator stabilite.

BIBLIOGRAFIE

1. David S.Jacobs et al. Laboratory Test Handbook, 3rd edition, Lexi-Comp Inc, 1994.

DIMENSIUNI DE KIT DISPONIBILE

Dimensiune kit	Număr de catalog
100 teste per kit	043100A

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire, RG6 4UT
Regatul Unit
Tel.: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 123789 0004 Rev. 00

Manufacturer:

Lorne Laboratories Ltd
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley, Berkshire RG6 4UT
UNITED KINGDOM

SRN Manufacturer - GB-MF-000029354

Authorized Representative:

Advena Ltd.
Tower Business Centre,
2nd Floor, Tower Street,
Swatar, BKR 4013, MALTA

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V13 123789 0004 Rev. 00

Report No.: 75959970_AR
Valid from: 2025-05-07
Valid until: 2030-05-06

Marta Carnielli
Head of Certification IVD

Issue date: 2025-05-07

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BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 123789 0004 Rev. 00

Classification:	Class D
Device Group:	IVR 0101 - Immunohaematology (Blood grouping): ABO system
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-

Rev.	Dated	Report	Description
00	2025-05-07	75959970_AR	Initial issuance

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