CERTIFICATE OF REGISTRATION

Digitally signed by Ceaicovschi Tudor
Date: 2023.04.07 10:10:27 EEST
Reason: MoldSign Signature
Location: Moldova

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:
0089217-01

Initial Certification Date:
2019-04-19

Date of Certification Decision:
2022-03-24

Certification Effective Date:
2022-04-18

Certification Expiry Date:
2025-04-18

Calin Moldovean
President, Business Assurance

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

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

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, Na/K/Cl/Ca/Li
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

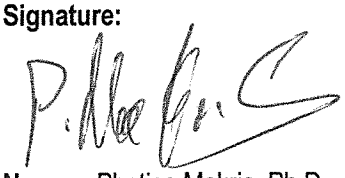
EC REP Emergo Europe, Molenstraat 15
NL-2513 BH The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are 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 and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, December 10, 2014

Signature:



Name: Photios Makris, Ph.D.
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/Product Name	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
2004	EasyLyte Analyzer	21 07 11 02
2014	EasyLyte Plus Analyzer	21 07 11 02
2015	EasyLyte Li+ Analyzer	21 07 11 02
2016	EasyLyte Calcium Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Na/K/Cl/Ca/Li Analyzer	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 Refrence Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
L2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
L2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
L2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
L2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
L2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
L2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
L2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
L2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
L2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
L2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
2124	EasyLyte Na/K/Cl/Ca/Li 800mL 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

EasyLyte Accessories, continued

Catalog No.	Accessory/Product Name	EDMA Code
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
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 Maintenance 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

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sorocovici Sergiu

Of Global Biomarketing Group

has completed training for the operation and service of the EasyLyte, EasyBloodGas, and EasyStat analyzers.

November 25, 2004

Date

MEDICA CORPORATION CORPORATE SEAL MASSACHUSETTS 1965

MEDICA

Randall Rollins

Signed: Randall Rollins
Technical Service Manager

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.

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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*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

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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APTACA S.p.A.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacuaptaca.it

P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE
CE DECLARATION OF CONFORMITY
DECLARAÇÃO CE CONFORMIDADE

La sottoscritta Aptaca S.p.A. con Sede Legale in via Monte Bianco, 4 - Monza (MB) Italia e Sede Operativa in Regione Monforte, 30 - Canelli (AT) Italia

The undersigned Aptaca S.p.A. with registered office at via Monte Bianco, 4 - Monza (MB) Italy and operational headquarters at Regione Monforte, 30 - Canelli (AT) Italy

O abaixo assinado Aptaca S.p.A. com sede na via Monte Bianco, 4 - Monza (MB) Itália e sede operacional na Regione Monforte, 30 - Canelli (AT) Itália

Dichiara sotto la sua unica responsabilità che i Dispositivi Medici di seguito descritti:

Declares under its sole liability that Medical Devices described as follows:

Declara sob sua única responsabilidade que os dispositivos medicos a seguir descriminados como:

BASIC UDI-DI (Global Model Number – GMN): 805577609FT19HOLDER01J2

UDI-DI: 8055776090016

Camicia (holder) in polipropilene, monouso REF. 31300

Holder in PP, disposable REF. 31300

Suporte de polipropileno, descartável, REF. 31300

Holder monouso, non sterile, destinato ad essere utilizzato in combinazione con un ago per il prelievo di sangue con provette sottovuoto. Solo per uso professionale.

Holder disposable, no sterile, intended to be used in combination with a needle for vacuum tube for blood sampling. For professional use only.

Suporte descartável e não estéril destinado a ser usado em combinação com uma agulha para coleta de sangue com tubos a vácuo. Apenas para uso profissional.

Classificazione del dispositivo: Classe I - Allegato 8, capo 3 del Regolamento UE 2017/745 (MDR) regola 1. Il dispositivo è conforme al Regolamento UE 2017/745 (MDR).

Device classification: Class I - Annex 8, chapter 3 of EU Regulation 2017/745 (MDR) rule 1. The Device is conform to EU Regulation 2017/745 (MDR).

Classificação do dispositivo: Classe I - Anexo 8, capítulo 3 do Regulamento da UE 2017/745 (MDR) regra 1. O dispositivo está em conformidade com o Regulamento da UE 2017/745 (MDR).

Rilasciato / *Released*
Canelli, 01.04.2022

Giulio BUONO
Quality Assurance and Regulatory Affairs Manager
In nome e per conto del Legale Rappresentante
Simone BUONO

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
06.04.2021

ARTICOLO: **AGHI MULTIPLI**
ITEM: ***MULTI-SAMPLES NEEDLES***

DESCRIZIONE / *DESCRIPTION*

Aghi multipli in acciaio a parete ultrasottile per sistemi di prelievo sottovuoto.
Il disegno delle pareti degli Aghi garantisce un flusso di sangue maggiore e più costante. Il sistema di chiusura con valvola nella parte prossimale dell'ago riduce la contaminazione ogni volta che una provetta viene estratta dalla camicia.
I bordi perfettamente affilati ed il disegno esclusivo permettono di penetrare i tessuti con un'incisione che minimizza il trauma per il paziente e garantiscono maggiore confort ed affidabilità. La particolare affilatura permette di limitare lo stress per il paziente mentre viene mantenuta la qualità del campione di sangue. La siliconatura consente all'ago di muoversi dolcemente dal momento della penetrazione dei tessuti sino a quello dell'estrazione. Dispositivi sterili, apirogeni, latex-free, confezionati singolarmente in custodie di polipropilene di due pezzi, sigillato con una etichetta a strappo "sigillo di integrità"

Multi-Samples needles in ultra thin steel wall for vacuum system collection
Multi-sample needles optimise patient's comfort during venepuncture. Due to their sharp tip and unique, double bevel design, tissue damage and thromboplastin release is minimal and trauma during incision very low. The unique needle coating allows the needle to travel smoothly from the moment of penetration until its withdrawal. A special valve design and composition reduces the contamination risk significantly by tightly closing the distal end of the needle each time a tube is removed. Multi-Samples needles allow increased blood-flow rates due to their larger inner diameter and significantly decrease risks of haemolysis during venepuncture - ensuring consistently reliable test results Sterile, Non pyrogenic and latex-free devices. Each needle is individually wrapped with a polypropylene cover composed by 2 parts and sealed with a label as "integrity seal".

Prodotto con marchio CE - conforme alla Direttiva 93/42/CE e al D.lgs 46 del 24/02/1997
CE Marked product – manufactured in compliance with 93/42/CE Directive and D.lgs 46 dtd 24/02/1997

COMPATIBILITA' / *COMPATIBILITY*

Gli aghi sono destinati ad essere utilizzati con: una camicia (holder) per singolo paziente; una o più provette con vuoto predeterminato, per singolo paziente. Gli aghi sono compatibili con i principali sistemi equivalenti presenti nel mercato.

Needles must be used with: One holder; One or more vacuum tubes for a single patient.
Our needles are compatible with the equivalent main systems present in the market.

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CARATTERISTICHE PRINCIPALI / *TECHNICAL FEATURES*	
Stato microbiologico ***Microbilogical status***	**STERILE / *STERILE*** OSSIDO DI ETILENE / *ETHILENE OXIDE*
Ago ***Needle***	ACCIAIO INOX AISI 304 SILICONATO *STAINLESS STEEL CANNULA (AISI 304)*
Custodia ***Plastic cover***	**Materiale / *Material:*** polietilene / *polyethylene*
Filetto per ago ***Hub***	**Materiale / *Material:*** Polipropilene / *Polypropylene*
Gommino copriago ***Rubber sleeve***	**Materiale / *Material:*** Gomma isoprene di colore grigio / *Grey Isoprene Rubber*
Validità del prodotto ***Shelf life***	60 MESI / *MONTHS*

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO" di Classe IIa sterile (Direttiva 93/42/CE e s.m.i.) – Aghi per il prelievo di sangue. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale Dispositivi Medici (CND) > A010105 (AGHI PER PRELIEVO SOTTO VUOTO)

Intended purpose is "MEDICAL DEVICE" Class IIa sterile (Directive 93/42/ECC) – Blood collection needles. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > A010105 (*NEEDLES, CLOSED SYSTEMS COLLECTING).*

COD. 31118

DIMENSIONI	*DIMENSIONS*
18 G x 1" 1,2 x 25 mm	
COLORE	***COLOUR***
Rosa / *Pink*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	***PACKAGING***
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736521/R	

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COD. 31218

DIMENSIONI	*DIMENSIONS*
18 G x 1 ½ ” 1,2 x 38 mm	
COLORE	***COLOUR***
Rosa / *Pink*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	***PACKAGING***
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736515/R	

COD. 31120

DIMENSIONI	*DIMENSIONS*
20 G x 1” 0,9 x 25 mm	
COLORE	***COLOUR***
Giallo / *Yellow*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	***PACKAGING***
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736523/R	

COD. 31220

DIMENSIONI	*DIMENSIONS*
20 G x 1 ½ ” 0,9 x 38 mm	
COLORE	***COLOUR***
Giallo / *Yellow*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736522/R	

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COD. 31121

DIMENSIONI	*DIMENSIONS*
21 G x 1” 0,8 x 25 mm	
COLORE	***COLOUR***
Verde / *Green*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736526/R	

COD. 31221

DIMENSIONI	*DIMENSIONS*
21 G x 1 ½ ” 0,8 x 38 mm	
COLORE	***COLOUR***
Verde / *Green*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736525/R	

COD. 31122

DIMENSIONI	*DIMENSIONS*
22 G x 1” 0,7 x 25 mm	
COLORE	***COLOUR***
Nero / *Black*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736528/R	

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COD. 31222

DIMENSIONI	*DIMENSIONS*
22 G x 1 ½ ” 0,7 x 38 mm	
COLORE	***COLOUR***
Nero / *Black*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736527/R	

COD. 31123

DIMENSIONI	*DIMENSIONS*
23 G x 1” 0,6 x 25 mm	
COLORE	***COLOUR***
Blu / *Blue*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736531/R	

COD. 31223

DIMENSIONI	*DIMENSIONS*
23 G x 1 ½ ” 0,6 x 38 mm	
COLORE	***COLOUR***
Blu / *Blue*	
CONFEZIONI INTERNE	***INNER BOX***
100 pezzi / *pieces* 110 x 80 x 68 mm - 0,2 Kg.	
CONFEZIONI	**CONFEZIONI**
1.000 pezzi / *pieces* (10 x 100 pcs) 353 x 167 x 121 mm – 2,3 Kg.	
Repertorio Nazionale dei Dispositivi Medici (RDM)	
1736530/R	

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STOCCAGGIO E CONSERVAZIONE / *STORAGE AND PRESERVATION:*

Lo stoccaggio e la conservazione degli aghi per lungo tempo deve avvenire ad una temperatura compresa in un range da +0 a +40 °C, in luogo asciutto.

Needles storage and preservation for long time should be at a temperature between +0° and +40°C, in a dry place.

MODALITÀ DI SMALTIMENTO / *DISPOSAL MODALITY:*

Smaltire secondo le normative vigenti

Dispose according to existing regulations

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

4426

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC

Check Certificate Status: here

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

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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

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

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	044150A
500 Tests Per Kit	044500A

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E-mail: info@lornelabs.com

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

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