STATEMENT

We, **Rapid Labs Limited** having a registered office at Unit 2 & 2A, Hall Farm Business Centre, Church Road, Little Bentley, Colchester, Essex CO7 8SD, United Kingdom assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: March 5th, 2025

Signature: Tracy Wu Rapid Labs Rapid Labs Limited

Digitally signed by Dolgopol Iulian
Date: 2025.12.08 09:49:33 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Unit 2 & 2A, Hall Farm Business Centre,
Church Road, Little Bentley, Colchester,
Essex CO7 8SD, United Kingdom

Certificate of Registration

This certificate has been awarded to

Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Please refer to the Appendix

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by Mukesh Singhal - On behalf of the Schemes Manager

Appendix to Certificate

Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles

Certificate Number **55321/A/0001/UK/En**

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Issued by

Mukesh Singhal - On behalf of the Schemes Manager

CE

Rapid Labs

Declaration of Conformity

for Syphilis reagents & kits

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

In accordance with Article 9(1) and by reference to Annex III, Rapid Labs Ltd has assessed the conformity for the following listed devices to the essential requirements of Directive 98/79/EC of the European Parliament and of the Council of the European Union on *in vitro* diagnostic medical devices.

General Product Name:	Syphilis reagents & kits
Manufacturer:	Rapid Labs Ltd. Unit 2 & 2a Hall Farm, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
Variants:	n/a
Intended Use:	The kits and reagents uses serum or plasma samples in the detection of *T.Pallidum* antibodies.
Intended User:	Professional use
IVD Directive Category:	General
Notified Body:	n/a
CE Certificate Reference:	n/a
IVD Directive Assessment Route:	Annex III
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Rowland King **Position** Managing Director

Signed **Date** 04/02/2022

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

CE

Rapid Labs

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 13612:2002	Performance evaluation of in-vitro medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in-vitro diagnostics
EN ISO 15223-1:2016	Medical devices - Symbols
EN ISO 23640:2015	Evaluation of stability

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
RL-VDRL250	VDRL Carbon Antigen Kit with no accessories	51819
D-RPR100 D-RPR250 D-RPR500	RPR Test Kit	51819
RL-TPHA100 RL-TPHA200 RL-TPHA500	TPHA Test Kit (haemagglutination)	51800
RL-TPHA-PC-1	TPHA positive control	51800
RL-TPHA-NC-1	TPHA Negative control	51800
RL-RPR5ML	VDRL (RPR) Carbon Reagent	51821
RL-RPRP1ML	RPR Positive Control	32449
RL-RPRN1ML	RPR Negative Control	32449

Version History

Version	Compiled by	Date	Description
2.0	Emily Swager	04/02/2022	Update to director

RAPID BIOTEC™ CE IVD

RPR Test Kit

– 100, 250 & 500 Tests

Cat. No.	Product Description
D-RPR500	RPR 500 Test Kit
D-RPR250	RPR 250 Test Kit
D-RPR100	RPR 100 Test Kit

INTENDED USE

Intended for the qualitative detection of reagin antibodies in human serum and EDTA plasma as an aid in the diagnosis of syphilis. The intended use population is patients with a suspected syphilis infection or at elevated risk of syphilis infection who attend STI clinics or other healthcare settings. This assay is not intended for automated use. This assay is not intended for blood screening or as a confirmatory assay on donor samples.

PRINCIPLE OF THE TEST

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons. RPR measures IgM & IgG antibodies to lipoidal material released from damaged host cells as well as possibly cardiolipin released from treponemes. If antibodies are present, they combine with lipid particles of the antigen, causing them to aggregate. The carbon particles appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non aggregated pattern which may form buttons in the centre of the test area.

KIT CONTENTS

Kit size (no. of tests)	100	250	500
RPR Carbon Antigen	2ml	5ml	10ml
Positive Control	1ml	1ml	1ml
Negative Control	1ml	1ml	1ml
Stirrers	100	250	500
Test Slides	10	25	50
Dispensing Bottle	1	1	1
Dispensing tip	1	1	1
Pack insert (IFU)	1	1	1

MATERIALS REQUIRED, BUT NOT PROVIDED

Micropipettes capable of dispensing 50µl.
Rotator set at 90-110 r.p.m.

REAGENT PREPARATION

Bring all reagents and samples to room temperature before use.

STORAGE AND SHELF LIFE AFTER FIRST OPENING

Antigen and controls should be stored at 2–8°C. Do not freeze.
After opening Antigen and Controls are stable for up to 3 months when stored at 2–8°C.
Do not use after the expiration date.

WARNING & PRECAUTIONS

- RPR is for in vitro diagnostic use only. For professional use only.
- Antigen and Controls contain sodium azide (< 0.1% w/v) as a preservative, which can accumulate in lead or copper pipes to form potentially explosive azides. To prevent azide build-up, flush with large volumes of water after disposing of solutions containing azide into the drains.
- Refer to RPR Safety Data Sheet for detailed information on reagent chemicals.
- This device contains material of animal origin. All bovine material is origin certified from approved sources.
- Do not freeze Antigen and Controls.
- Reagents from the same lot may be pooled using good laboratory practices.
- Reagents showing visible signs of microbial growth or gross turbidity may indicate degradation and should be discarded according to local rules.
- The effects of microbial contamination in specimens cannot be predicted.
- Do not use reagents after the expiration date.
- Do not interchange caps between the Positive and Negative Control vials. Controls are differentiated by colour coded caps and the vial label. If caps are inadvertently switched, the Control tubes should be discarded.
- The reaction areas on the Test Cards should not be touched as this may invalidate results.
- Samples exhibiting gross lipemia, hemolysis or icterus may be compromised and may require alternative testing.
- Deviations from the RPR Instructions for Use can lead to erroneous results.
- Dispose of leftover reagents in a safe manner, in accordance with local regulations

SAMPLE COLLECTION, HANDLING & STORAGE

RPR may be used for testing with either human serum or EDTA plasma specimens for up to 7 days after collection. Specimens should be free of particulate matter to prevent interference with the assay result. If erythrocytes or other visible components are present in the specimen, remove by centrifugation to prevent interference with the test results. Store EDTA plasma and serum specimens at 2-8°C up to 7 days. EDTA plasma and serum specimens can be frozen at less than -20°C for up to one month, thawed and mixed thoroughly prior to testing. Specimens may be frozen and thawed up to 5 times. Allow all specimens to equilibrate to room temperature before use.

DIRECTIONS FOR USE

1) Place 50µl of sample into a circle marked on the test card.
2) Spread the sample evenly over the test circle area.(Note: The distance between the test circle area on the slide shall not be less than 0.5cm) The flat end of the pipsters can be used to spread the sample over the test circle.
3) Shake the vial of RPR antigen to ensure even mixing.
4) Attach the dropping needle to the plastic dropping bottle and take up the RPR antigen by suction.
5) Invert the dropper bottle containing antigen and gently squeeze to expel air from the needle.
6) Holding the dropper bottle vertically over the test sample dispense a single drop,17.5 µl, of antigen.
7) Place test card on a card rotator and rotate at 100 RPM for 8 minutes.
8) Read and interpret results visually in good light. See interpretation.
9) It is recommended that the kit positive and negative controls are run with each batch of test samples.
10) Return unused antigen from dropper bottle to glass vial.
11) Clean out dropper bottle and needle with distilled water and allow to dry before re-using.

Sample titration assay procedure

1) Make doubling dilutions from Undiluted to 1:16 in normal saline.
2) Place 50µl of each dilution in to a separate circle on the test card.
3) Spread each dilution evenly over the test circle. 4) Continue as from Assay procedure section (3). The titre of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

CONTROL PROCEDURE

The Positive and Negative Controls must be run with each assay. Additional QC testing may be performed by the operator by the inclusion of other characterised specimens or reference material. The Positive Control should produce a positive result and the Negative Control should produce a negative result with the test. If the appropriate results are not obtained with the controls, the assay is considered invalid and all samples within that assay should be

retested.

INTERPRETATION OF RESULTS

Strong reactive: Large clumps of carbon particles with a clear background

Reactive: Large clumps of carbon particles somewhat more disperse than strong reactive pattern

Weak Reactive: Small clumps of carbon particles with light Grey background

Trace reactive: Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.

Non-reactive: Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.

PERFORMANCE CHARACTERISTICS

Reproducibility

A panel of syphilis-negative samples and syphilis-positive samples of varying reactivity were tested twice per day for 5 days over a 7 day period using 3 reagent lots.

Samples	Agreement N=	Total N=	Rate of Agreement	95%CI
Syphills positive	250	250	100.00%	98.54-100%
Syphills negative	50	50	100.00%	92.89-100%
Over all	300	300	100.00%	98.78-100%

Cross reactivity and interference

At least 9 syphilis positive samples and 9 syphilis negative samples from patients with a variety of potentially interfering diseases and conditions were tested using 3 different lots of RPR reagents in order to determine whether these diseases or conditions cause positive or negative analytical interference. Cross reactivity and interference of Rubella, Toxoplasma, Borrelia, EBV, HCV, HBV, HAV, HIV, HTLV, Herpes, Chlamydia), ANA antibodies, Rheumatoid Factor antibodies and samples from pregnant (multiparous) subjects were tested. All samples tested (151 syphilis positives and 140 syphilis negatives) showed concordance with the clinical status of the sample.

Diagnostic sensitivity

The diagnostic sensitivity for RPR was calculated for 168 samples (37 EDTA plasma and 131 sera) which had been confirmed as RPR positive by two other CE marked assays for non-treponemal antibodies

Sample	Agreement measure	Agreement N=	Total N=	ROA (%)	95%CI (%)
EDTA Plasma	Sensitivity	37	37	100%	90.51-100.00
Sera	Sensitivity	131	131	100%	97.22-100.00
All Samples	Sensitivity	168	168	100%	97.83-100.00

Diagnostic specificity

The false positive rate of RPR was compared with another CE-marked assay for non-treponemal antibodies associated with syphilis infection using known syphilis-negative samples.

		RPR	
		R	NR
CE Marked RPR	R	0	0
	NR	0	1246

R: Reactive

NR: Non-Reactive

NPA agreement for RPR and alternative RPR product

Sample	Agreement measure	Agreement N=	Total N=	ROA (%)	95%CI (%)
EDTA Plasma	NPA	1246	1246	100%	99.70-100.0%

LIMITATIONS

Pinta, yaws, bejel and other treponemal diseases may produce reactive results with non-treponemal tests.

RPR is intended for use as an aid to diagnosis. Results should be interpreted in combination with other serological test results and clinical evaluation.

POST MARKET SURVEILLANCE

Should this IVD be implicated in any serious incident a report shall be made to the manufacturer and competent authority of the Member State in which the user and/or the patient is established.

SUMMARY OF SAFETY AND PERFORMANCE

SSP can be obtained from the EUDAMED website

Index of Symbols

	Consult instructions for use	IVD	*In vitro* diagnostic medical device
REF	Catalogue number	LOT	Batch code
2°C 8°C	Store between 2-8°C		Use-by date
	Manufacturer		Date of manufacture
Σ	Contains sufficient for <*n*> test	EU REP	European Authorized Representative

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

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Revision 1 20/11/2025