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: 2026.01.09 09:20:03 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

If there is any doubt as to the authenticity of this certificate, please do not hesitate to contact the Head Office of the Group on info@urs-certification.com.
URS is a member of United Registrar of Systems (Holdings) Ltd, United House, 28 Poole Hill, Bournemouth BH2 5PS, UK. Company Registration no. 5298466

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**

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'.

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Issued by

Mukesh Singhal - On behalf of the Schemes Manager

CE

Rapid Labs

Declaration of Conformity

for Latex and slide agglutination 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:	Latex and slide agglutination 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 Rapid Labs Latex agglutination are tests consisting of antigen/antibody coated latex particles for the detection of infectious, physiological or auto immune conditions.
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-ASO100 RL-ASO50	ASO Latex Test Kit with accessories	63271
RL-ASO100NA RL-ASO50NA	ASO Latex Test Kit w. No Accessories	63271
RL-CRP100 RL-CRP50	CRP Latex Test Kit with accessories	63234
RL-CRP100NA RL-CRP50NA	CRP Latex Test Kit w. No Accessories	63234
RL-RA100 RL-RA50	RA (RF) Latex Test Kit with accessories	55112
RL-RA100NA RL-RA50NA	RA (RF) Latex Test Kit w. No Accessories	55112
RL-LE100 RL-LE50	Systemic Lupus Erythematosus Latex test kit	54853
RL-MONO50	Mononucleosis Latex Kit	49688
RL-STA50 RL-STA100	Staphylococcus Latex Kit	51659
RL-RB100	Rose Bengal Agglutination Kit	50601
RL-WR100	Waaler Rose Haemmaglutination Kit	55112

Version History

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

RAPID BIOTEC™

Instructions for use
SLE Latex Test Kit

SLE Latex Test Kit

Slide Test for Anti-Deoxyribonucleoprotein

CE

REF	RL-LE100/50
Σ	100/50

8°C 2°C Store at 2-8°C	Manufacturer	LOT Batch Number	REAGENT Description of reagent
Use by (Last day of stated month)	Consult Instructions for use	This way up	Xn NaN, R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment.
Date of Manufacture	REF Catalogue Number	IVD In vitro Diagnostic Medical Device	

SUMMARY

The presence of autoantibodies to nuclear proteins is a common finding in Systemic Lupus Erythematosus (SLE) and other collagen diseases.

Anti-DNP is present in high titres in the serum of majority of SLE patients with active disease but is present occasionally in remission states. Although Anti-DNP is found exclusively in SLE, only low titres may be detected in diseases such as chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma and drug hypersensitivity.

SLE is a latex agglutination slide test for the detection of antibodies to dsDNA and histones.

REAGENTS

1. SLE reagent is a uniform suspension of polystyrene latex particles coated with Deoxyribonucleoprotein (DNP).
2. Positive control, reactive with SLE reagent.
3. Negative control, non-reactive with SLE reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

Store the reagent at 2-8°C. DO NOT FREEZE. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Do not use reagents after the expiry date

PRINCIPLE

Latex particles coated with DNP will agglutinate when mixed with serum containing Anti-DNP. No agglutination indicates absence of Anti-DNP in the serum.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. The reagents contain sodium azide 0.1 % as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or exposure to extreme temperatures. It is strongly recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.
5. Shake the latex reagent well before use to disperse the latex particles uniformly and to improve test readability.
6. Only a clean and dry slide must be used. Clean the slide with distilled water thoroughly and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.
8. Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Use fresh clear serum samples. In case of delay in testing, store the serum samples at 2-8°C for upto 72 hours. For longer storage freeze the serum. However, repeated freezing and thawing of samples should be avoided.

ADDITIONAL MATERIAL REQUIRED

Test tube (10 x 75 mm), Pipettes, Isotonic saline, Stopwatch, Direct light source.

TEST PROCEDURE

Bring all reagents and samples to room temperature before use.

Qualitative Method

1. Place one drop (40 µl) of sample to be tested onto one of the reaction circles of the slide using a sample dispensing pipette provided with the kit.
2. Place one drop of positive and negative control onto separate reaction circles of the slide.
3. Gently shake the SLE latex reagent and add one drop to each sample and control taken on the slide.
4. Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **three minutes**.

Semi Quantitative Method.

1. Using isotonic saline prepare serial dilutions of the serum sample 1:2, 1:4, 1:8, 1:16,1:32 and so on.
2. Place each dilution of the serum sample onto separate reaction circles of the slide.
3. Add one drop of well mixed SBio SLE latex reagent to each dilution of the sample on the slide.
4. Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
5. Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at **three minutes**.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates presence of Anti-DNP in the test specimen.

No agglutination is a negative test res **Semi Quantitative Method**

The titre of the serum is the reciprocal of the highest dilution, which gives agglutination.

REMARKS

1. Markedly lipemic, haemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Anti-DNP may be found in diseases other than SLE. Low titres have been detected in rheumatoid arthritis, chronic hepatitis, periarteritis nodosa, dermatomyositis, scleroderma, atypical pneumonia, tuberculosis and lymphoma.

PERFORMANCE CHARACTERISTICS

1. The performance characteristics of SLE were evaluated using known positive and negative samples. The known samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	SLE	
		Positive	Negative
SLE +ve samples	33	33	0
SLE -ve samples	80	0	80
	113	33	80

Sensitivity: 100% Specificity: 100%

2. Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of SLE negative and SLE positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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Doc Ref: SLE Kit RB 1 - 06/2024

Manufactured in UK, by :
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Unit 2, Hall Farm, Church Road, Little Bentley, Colchester.
CO7 8SD. U.K.