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

Digitally signed by Ceaicovschi Tudor
Date: 2022.02.04 15:00:50 EET
Reason: MoldSign Signature
Location: Moldova

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

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

LORNE LABORATORIES LTD

RELEASE PROTOCOL

CE 1434

PRODUCT:	Anti-D Duoclone Monoclonal Blood Grouping Reagent
LOT NUMBER:	740177-C1 and all sub-lots (i.e. 740177-C2, 740177-C3, 740177-C4, etc)
MANUFACTURE DATE:	2020-12-10
EXPIRY DATE:	2023-06-10
PRESERVATIVE:	<0.1% Sodium Azide w/v
DYE:	None
STERILITY:	Product filtered through a sterile 0.2 μm filter
STORAGE:	Refrigerate at 2 – 8°C
MICRO TESTING:	Source materials used to produce this lot were tested at source and found to be non-reactive for anti-HIV 1+2, anti-HCV and HBsAg.

POTENCY:

	Tube Test	BioVue Card	DiaMed Card	Microplate
O R_1r Cells	1 in 128	1 in 256	1 in 512	1 in 64

AVIDITY: (1st sign of agglutination) **O R_1r Cells** 6 seconds **R_2r Cells** 5 seconds

SPECIFICITY:

Positive Phenotypes		Negative Phenotypes	
O R_1r Cells	Grade 5	**r'r Cells**	Negative
R_2r Cells	Grade 5	**r"r Cells**	Negative
Weak D (D^u) Cells	Grade 4	**rr Cells**	Negative
Variant D^{VI} Cells	Grade 5		

QUALITY CONTROL: This lot of Anti-D Duoclone conforms to the specifications stated in the current issue of "The Guidelines for the Blood Transfusion Services in the UK" and the Common Technical Specifications (CTS)

RELEASED BY: **DATE:** 18 January 2021

(Laboratory Manager or Nominee)

CERTIFICATE

Certificate No. 1434-V-024/2021

Product Verification

Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the device manufactured by:

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

i.e. *in vitro* diagnostic medical device List A

Anti-D Duoclone Monoclonal 740010

LOT number: 740177-C1 inc. all sub-lots produced according to Lorne procedure GENSOP0102
Lot size: 10000 x 10mL
Date of expiry: 10-06-2023
Name of the laboratory: N/A
Number of the report/opinion/declaration: N/A
Date of the report: 14-01-2021

Complies with requirements
of Annex IV (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law

The date of issue of the Certificate: 15-01-2021

CE 1434

Contract No: MD-59/2019

Elektronicznie podpisany przez Monika Elżbieta Mroczkiewicz
Data: 2021.01.15 08:19:11 +01'00'

Deputy Director
Medical Devices Certification Department

POLISH CENTER FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, email: pcbc@pcbc.gov.pl

LORNE LABORATORIES LTD

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Email: info@lornelabs.com

CERTIFICATE OF ANALYSIS

DESCRIPTION	LOT NO.	EXPIRY	PRODUCT CODE
ASO Latex Kit	**LO16126**	**2023-01**	**031100A**

STORAGE: Refrigerated at 2 – 8ºC. Protect from light. Do not freeze.

SHIPPING: This product has data supporting stability tolerance during fluctuations in ambient shipping temperature.

This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications.

REAGENT	SPECIFICATIONS			RESULT
	Appearance	Colour	Functionality	
ASO Latex Reagent	Homogeneous suspension free of macroscopic or flaky particles	White	Tested against kit (+) and (-) controls	**PASS**
Positive Control Negative Control	Liquid solution	Clear and transparent		**PASS**

If applicable:

- Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. Handle with caution as potentially infectious.
- This product was tested by methods described in the manufacturers package insert.
- This product is intended for ***In Vitro*** Diagnostic use only.

We certify that this product has been released as meeting our acceptance criteria

APPROVED BY: **DATE: 07 April 2021**

Eddy Velthuis
Technical Director

LORNE LABORATORIES LTD

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CERTIFICATE OF ANALYSIS

DESCRIPTION	LOT NO.	EXPIRY	PRODUCT CODE
CRP Latex Kit	**LO16128**	**2023-02**	**850100A**

STORAGE: Refrigerated at 2 – 8°C. Protect from light. Do not freeze.

SHIPPING: This product has data supporting stability tolerance during fluctuations in ambient shipping temperature.

This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications.

REAGENT	SPECIFICATIONS			RESULT
	Appearance	Colour	Functionality	
CRP Latex reagent	Homogeneous suspension free of macroscopic or flaky particles	White	Tested against kit (+) and (-) controls	**PASS**
Positive Control Negative Control	Liquid solution	Clear and transparent		**PASS**

If applicable:

- Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. Handle with caution as potentially infectious.
- This product was tested by methods described in the manufacturers package insert.
- This product is intended for ***In Vitro*** Diagnostic use only.

We certify that this product has been released as meeting our acceptance criteria

APPROVED BY: **DATE: 24 March 2021**

Eddy Velthuis
Technical Director

LORNE LABORATORIES LTD

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CERTIFICATE OF ANALYSIS

DESCRIPTION	LOT NO.	EXPIRY	PRODUCT CODE
RF Latex Kit	**LO16258**	**2022-05**	**830100A**

STORAGE: Refrigerated at 2 – 8ºC. Protect from light. Do not freeze.

SHIPPING: This product has data supporting stability tolerance during fluctuations in ambient shipping temperature.

This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications.

REAGENT	SPECIFICATIONS			RESULT
	Appearance	Colour	Functionality	
RF Latex reagent	Homogeneous suspension free of macroscopic or flaky particles	White	Tested against kit (+) and (-) controls	**PASS**
Positive Control Negative Control	Liquid solution	Clear and transparent		**PASS**

If applicable:

- Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. Handle with caution as potentially infectious.
- This product was tested by methods described in the manufacturers package insert.
- This product is intended for ***In Vitro*** Diagnostic use only.

We certify that this product has been released as meeting our acceptance criteria

APPROVED BY: **DATE: 08 September 2020**

Eddy Velthuis
Technical Director