EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of in vitro diagnostic reagents for identification of blood groups

Device Classification:
Annex II, List A and B

Device Descriptions:
Please refer to Attachment 1

Model:
Please refer to Attachment 1

File Number	A12241	Cycle Start Date	23 May 2017
Certificate No.	354.170425	Effective Date	23 May 2017
		Expiry Date	22 May 2022

Digitally signed by Ceaicovschi Tudor
Date: 2022.02.24 17:59:02 EET
Reason: MoldSign Signature
Location: Moldova

Authorised by

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248 , following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.

Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
Anti-A Monoclonal	600005/600010/600000	Annex II List A
Anti-B Monoclonal	610005/610010/610000	Annex II List A
Anti-A,B Monoclonal	620005/620010/620000	Annex II List A
Anti-C Monoclonal	690005	Annex II List A
Anti-E Monoclonal	691005	Annex II List A
Anti-c Monoclonal	692005	Annex II List A
Anti-e Monoclonal	693005	Annex II List A
Anti-K Monoclonal	760005/760010	Annex II List A
Anti-D Clone 2 Monoclonal	710010/710000	Annex II List A
Anti-D Clone 1 Monoclonal	730010/730000	Annex II List A
Anti-D Duoclone Monoclonal	740010/740000	Annex II List A
Anti-Jka Polyclonal	323002/323000	Annex II List B
Anti-Jkb Polyclonal	324002/324000	Annex II List B
Anti-Fyb Polyclonal	317002/317000	Annex II List B
AHG Elite Clear	415010/415100/415000	Annex II List B
AHG Elite Green	435010/435100/435000	Annex II List B
Anti-Fya Monoclonal	774000/774002	Annex II List B
Anti-C+D+E Monoclonal	700005/700010/700000	Annex II List A
Anti-Human IgG Clear	401010/401000	Annex II List B
Anti-Human IgG Green	402010/402000	Annex II List B
Monoclonal Rh Control	640010	Annex II List A
Monoclonal D Negative Control	650010	Annex II List A

File Number A12241
Certificate No. 354.170425

Cycle Start Date 23 May 2017
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Authorised by

B. Rodgers
Certification Manager
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Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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

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

Unit 1 Cutbush Park Industrial Estate
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United Kingdom

Phone: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com

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

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

CERTIFICATE

EC No 1434-IVDD-132/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate, Danehill, Lower Earley, Berkshire RG6 4UT, United Kingdom

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List B

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 22.03.2022

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Application No: 648/2019
Module: H7

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No **1434-IVDD-132/2019**
Issued under the Contract No MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-132/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-Jka Polyclonal 323002	52586
Anti-Jkb Polyclonal 324002	52587
Anti-Fyb Polyclonal 317002	52570
AHG Elite Clear 415010	52731
AHG Elite Green 435010	52731
Anti-Fya Monoclonal 774002	52569
Anti-Human IgG Clear 401010	45811
Anti-Human IgG Green 402010	45811
Anti-Jka Monoclonal 775002	52586
Anti-Jkb Monoclonal 776002	52587

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-132/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019

LORNE LABORATORIES LTD

Unit 1 Cutbush Park Industrial Estate
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Phone: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com

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