LORNE LABORATORIES LTD

CERTIFICATE OF ANALYSIS

CE 1434

PRODUCT:	Anti-D Duoclone Monoclonal Blood Grouping Reagent
LOT NUMBER:	740181-C1 and all sub-lots (i.e 740181-C2, 740181-C3, 740181-C4, etc)
MANUFACTURE DATE:	2022-01-11
EXPIRY DATE:	2024-07-11
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 64	1 in 256	1 in 512	1 in 128

AVIDITY: (1st sign of agglutination) **O R_1r Cells** 3 seconds **R_2r Cells** 4 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 3	**rr Cells**	Negative
Variant D^{VI} Cells	Grade 4		

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:** 09 February 2022

Technical Administrator

Digitally signed by Ceaicovschi Tudor
Date: 2022.06.14 10:51:26 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

Certificate No. 1434-V-064/2022

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: 740181-C1 inc. all sub-lots produced according to Lorne procedure GENSOP0102
Lot size: 11771 x 10 mL
Date of expiry: 11-07-2024
Name of the laboratory:
Number of the report/opinion/declaration:
Date of the report: 08-02-2022

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: 09.02.2022

CE 1434

Contract No: MD-59/2019

Marcin Pruchniak

Elektronicznie podpisany przez Marcin Pruchniak
Data: 2022.02.09 14:10:16 +01'00'

Manager
In Vitro Medical Devices
Certification Team

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

CERTIFICATE

EC No 1434-IVDD-133/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Lorne Laboratories Ltd

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

in vitro diagnostic medical devices
List A

Products list in attachments: 1

in terms of design documentation, comply with requirements of Annex IV section 4 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 23.05.2023

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: 649/2019
Module: H6

mgr Anna Wyroba
Vice-President

Certificate No **1434-IVDD-133/2019**
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-133/2019

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

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-133/2019**
Issued under the Contract No. MD-59/2019
Bears the PCBC hologram.
Warsaw, 10.04.2019