



CERTIFICATE

EC No 1434-IVDD-134/2019
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 A

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 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



Application No: 649/2019
Module: H7


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-134/2019**
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-134/2019

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




mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-IVDD-134/2019**
Issued under the Contract No. **MD-59/2019**
Bears the PCBC hologram.
Warsaw, 10.04.2019