



CERTIFICATE

EC Certificate No. 1434-IVDD-027/2022

**Full Quality Assurance System
Directive 98/79/EC concerning
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 device
List B

The list of medical devices covered by this certificate is provided in the Annex 1

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

Validity of the Certificate: from 23.03.2022 to 27.05.2025

The date of issue of the Certificate: 03.03.2022

The date of the first issue of the Certificate: 10.04.2019



Issued under the Contract No. MD-173/2021
Application No: 577/2022
Certificate bears the qualified signature.
Warsaw, 03/03/2022
Module H7

Aleksandra Kostrzewa Digitally signed
by Aleksandra
Kostrzewa

President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-027/2022

List of medical devices covered by the certificate:

Anti-Jka Polyclonal 323002

Anti-Jkb Polyclonal 324002

Anti-Fyb Polyclonal 317002

AHG Elite Clear 415010

AHG Elite Green 435010

Anti-Fya Monoclonal 774002

Anti-Human IgG Clear 401010

Anti-Human IgG Green 402010

Anti-Jka Monoclonal 775002

Anti-Jkb Monoclonal 776002

CE 1434

Issued under the Contract No. MD-173/2021
Application No: 577/2021
Certificate bears the qualified signature.
Warsaw, 03/03/2022

Aleksandra Kostrzewa Digitally signed
by Aleksandra
Kostrzewa

President