



# 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



Application No: 648/2019  
Module: H7

  
mgr Anna Wyroba  
Vice-President



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:**

<b>Anti-Jka Polyclonal 323002</b>	<b>52586</b>
<b>Anti-Jkb Polyclonal 324002</b>	<b>52587</b>
<b>Anti-Fyb Polyclonal 317002</b>	<b>52570</b>
<b>AHG Elite Clear 415010</b>	<b>52731</b>
<b>AHG Elite Green 435010</b>	<b>52731</b>
<b>Anti-Fya Monoclonal 774002</b>	<b>52569</b>
<b>Anti-Human IgG Clear 401010</b>	<b>45811</b>
<b>Anti-Human IgG Green 402010</b>	<b>45811</b>
<b>Anti-Jka Monoclonal 775002</b>	<b>52586</b>
<b>Anti-Jkb Monoclonal 776002</b>	<b>52587</b>



  
mgr Anna Wyroba  
Vice-President



Annex 1 to certificate No. **1434-IVDD-132/2019**  
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