



CERTIFICATE

EC No 1434-IVDD-293/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Rapid Labs Limited

**Unit 2 & 2a Hall Farm Business Centre
Church Road, Little Bentley
Colchester CO7 8SD, United Kingdom**

in vitro diagnostic medical devices
List A

List of devices covered by this certificate is given in the Annex no. 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 17.05.2019 to 23.05.2023

The date of issue of the Certificate: 17.05.2019



Application No: 697/2019
Module: H6


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-293/2019**
Issued under the Contract No **MD-105/2019**
Bears the PCBC hologram.
Warsaw, 17.05.2019



ANNEX 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-IVDD-293/2019

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

Anti-A Monoclonal, BC-A10/BC-A10X10

Anti-B Monoclonal, BC-B10/BC-B10X10


Anti-A, B Monoclonal, BC-AB10/BC-AB10X10

Anti-D Monoclonal (IgG & IgM), BC-D10/BC-D10X10

Anti A, B, AB, D (IgG & IgM) kit, BC-ABOD10

Anti A, B, D (IgG & IgM) kit, BC-ABD10

CE 1434


mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-IVDD-293/2019**
Issued under the Contract No. **MD-105/2019**
Bears the PCBC hologram.
Warsaw, 17.05.2019