



CERTIFICATE

EC No 1434-IVDD-352/2019
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:

National Health Service
Blood & Transplant (NHSBT)
14 Estuary Banks, Liverpool L24 8RB
United Kingdom

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List B

List of devices covered by this certificate is given in the Annexes no. 1 & 2

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 18.07.2019 to 11.12.2023

The date of issue of the Certificate: 18.07.2019



Application No: 659/2019
Module: H7


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-352/2019**
Issued under the Contract No **MD-112/2019**
Bears the PCBC hologram.
Warsaw, 18.07.2019



ANNEX 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-IVDD-352/2019

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

2 Cell antibody screen PR101

2 Cell antibody screen in CellStab PR102

2 Cell antibody screen in CellMedia PR103

rr Cell antibody screen in CellStab PR106

rr Cell antibody screen in CellMedia PR108

r'r and r''r Cell antibody screen in CellStab PR107

r'r and r''r Cell antibody screen in CellMedia PR109

Antibody ID panel products in Alsevers PR141/144/201/211

Antibody ID panel products in CellStab PR142/143/202/212

Antibody ID panel products in CellMedia PR162/163

Antibody ID panel products in LISP PR146

Antibody ID panel products papainised in Alsevers PR154

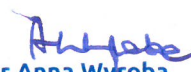
Antibody ID panel products papainised in CellStab PR152/153

Antibody ID panel products papainised in CellMedia PR172/173

IgG coated cells PR092

ZZAP Kit PN161




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Annex 1 to certificate No. **1434-IVDD-352/2019**
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ANNEX 2 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-IVDD-352/2019

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

Weak Anti-K Control PN043

Weak Anti-c Control PN042

Weak Anti-Fya Control PN044

Weak Anti-D Control PN046

AB Serum PN061

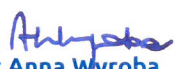
3 Cell antibody screen PR121

3 Cell antibody screen in CellStab PR122

3 Cell antibody screen in CellMedia PR123

3 Cell antibody screen papainised in Alsevers PR124




mgr Anna Wyroba
Vice-President



Annex 2 to certificate No. **1434-IVDD-352/2019**
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