



CERTIFICATE

EC Certificate No. 1434-IVDD-215/2022
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:

Alba Bioscience Ltd.

James Hamilton Way

Penicuik EH26 0BF, 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 24.05.2022 to 27.05.2025

The date of issue of the Certificate: 24.05.2022

The date of the first issue of the Certificate: 29.03.2019



Issued under the Contract No. MD-010/2022
Application No: 517/2022
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module H7

Tomasz Koeber

Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2022.05.24 11:59:01
+02'00'

Director
Medical Device Certification
Department



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-215/2022

List of medical devices covered by the certificate:

ALBAcyte® Reagent Red Cells for Antibody Screening, Z451
ALBAcyte® Reagent Red Cells for Antibody Identification (native, papainised), Z471, Z472
ALBAclone® Anti-Jkb, Z166
ALBAclone® Anti-Jka monoclonal, Z162
Polyspecific Anti-Human Globulin Reagent, Z350
Monospecific Anti-Human IgG, Z356
ALBAcyte® RhD Negative CAT Reagent Red Cells for Antibody Screening, Z466
ALBAclone® Anti-Fya, Z152
ALBAclone® Anti-Fyb, Z154
ORTHO™ Sera Anti-Fya Human Monoclonal IgG, 6904486 (FD151B)
ORTHO™ Sera Anti-Fyb Human Polyclonal IgG, 6904487 (FD153B)
ORTHO™ Sera Anti-Jka Human Monoclonal IgM, 6904488 (FD162B)
ORTHO™ Sera Anti-Jkb Human Monoclonal IgM 6904489 (FD166B)
ALBAcheck® BGS AlbaSure Sensitivity Control Kit – Z250
ALBAcheck® BGS Anti-D <0.1 IU/mL – Z262
ALBAcheck® BGS Anti-D 0.05 IU/mL – Z263
ALBAcyte® IgG Sensitised Reagent Red Cells – Z441
ALBAcheck® - BGS AB Serum (Human) – Z281

CE 1434

Issued under the Contract No. MD-010/2022
Application No: 517/2022
Certificate bears the qualified signature.
Warsaw, 24/05/2022

Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2022.05.24 11:59:23
+02'00'

Director
Medical Device Certification
Department