



CERTIFICATE

EC Certificate No. 1434-IVDD-133/2022

**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:

**National Health Service
Blood & Transplant (NHSBT)
14 Estuary Banks, Liverpool L24 SRB
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 02.05.2022 to 27.05.2025

The date of issue of the Certificate: 02.05.2022

The date of the first issue of the Certificate: 18.07.2019



Issued under the Contract No. MD-008/2022
Application No: 597/2021
Certificate bears the qualified signature.
Warsaw, 02/05/2022
Module H7

Aleksandra
Kostrzewa
President

Digitally signed by
Aleksandra Kostrzewa



Warsaw, 08.05.2024

BM.433.0597.2021/KW/MV/2024/0311

To Whom It May Concerns,

Polish Centre for Testing and Certification declares, that the list of in vitro diagnostic medical devices covered by the EC Certificate No. 1434-IVDD-133/2022, issued for National Health Service Blood & Transplant (NHSBT), 14 Estuary Banks, Liverpool L24 8RB United Kingdom has been limited from:

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
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

to:

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
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

Implementation of the change does not represent a significant change in design or intended purpose under IVDR 2017/746 Article 110(3) and the related IVDD Certificate No. 1434-IVDD-133/2022 issued 02.05.2022 remains valid until 27.05.2025.

Yours Sincerely,

Deputy Head
Medical Device Certification Department

Supplementary information to AR120 834771 - Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3

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

Date: 22 September 2025

Changes Approved:

Date	Reference Number	Action
22 September 2025	30535773	Transfer of appropriate surveillance to BSI per Regulation EU 2024/1860 of devices referenced in the Certificate Letter. Original NB Certificate Number: 1434-IVDD-133/2022.

22 September 2025

NHSBT Reagents
14 Estuary Banks
Speke
Liverpool
L24 SRB
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

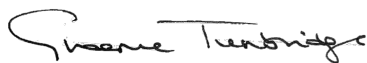
Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
1434-IVDD-133/2022	AR120 834771	98/79/EC Annex IV excluding Sections 4 and 6	30535773	Transfer of appropriate surveillance to BSI per Regulation EU 2024/1860 of devices: 2 Cell antibody screen PR101 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

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Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
1434-IVDD-133/2022	AR120 834771	98/79/EC Annex IV excluding Sections 4 and 6	30535773	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 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 Original NB Certificate Number: 1434-IVDD-133/2022

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices