

UKCA Certificate

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2025-05-22

Cycle start date

2025-05-22

Effective date

2025-05-22

Expiry date

2030-05-21

**UK Approved
Body
0843**

National Health Service Blood & Transplant (NHSBT)

14 Estuary Banks
Liverpool L24 8RB UNITED KINGDOM

UKCA Certificate – Full Quality Assurance System Approval Certificate

Part IV of The Medical Devices Regulations 2002, Annex IV excluding Sections 4 and 6
[as modified by Part 3 of Schedule 2A to The Medical Devices Regulations 2002]

Scope of Certificate:

Design, Manufacture and final inspection of reagents, control materials and
devices for determining blood groups and reagents for determining Irregular anti-
erythrocytic antibodies

**See Attachment(s) for devices referenced. Certificate with Attachment(s)
totals 2 pages.**

Authorized by:



Paul Daysh
Operations manager – Medical Regulatory



Check certificate status: [here](#)

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of Part IV of the UK Medical Device Regulations as specified above. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned regulation and is subject to periodic surveillance as required by Schedule 2A, Part 3. For Annex II, List A devices where they are covered by this certificate, a Design Examination certificate according to Part 3 of Schedule 2A is required.

UL International (UK) Limited
Units 1-4 Horizon, Kingsland Business Park, Wade Road
Basingstoke, RG24 8AH, United Kingdom

Attachment 1 of 1

Model/Type	Classification	G/UMDN Code
A1rr cells in Alsevers (10 mL 2.8% suspension) PR012	Annex II List A	-
A2rr cells in Alsevers (10 mL 2.8% suspension) PR022	Annex II List A	-
Brr cells in Alsevers (10 mL 2.8% suspension) PR033	Annex II List A	-
OR1r cells in Alsevers (10 mL 2.8% suspension) PR044	Annex II List A	-
A1rr cells in CellStab (10 mL 0.8% suspension) PR014	Annex II List A	-
A1rr cells in CellMedia (10 mL 0.8% suspension) PR015	Annex II List A	-
Brr cells in CellStab (10 mL 0.8% suspension) PR035	Annex II List A	-
Brr cells in CellMedia (10 mL 0.8% suspension) PR036	Annex II List A	-
BR1r cells in Alsevers (10 mL 2.8% suspension) PR034	Annex II List A	-
OR1r cells in CellStab (10 mL 0.8% suspension) PR045	Annex II List A	-
OR1r cells in CellMedia (10 mL 0.8% suspension) PR046	Annex II List A	-
2 Cell antibody screen in Alsevers PR101	Annex II List B	-
2 Cell antibody screen in CellStab PR102	Annex II List B	-
2 Cell antibody screen in CellMedia PR103	Annex II List B	-
3 Cell antibody screen in Alsevers PR121	Annex II List B	-
3 Cell antibody screen in CellStab PR122	Annex II List B	-
3 Cell antibody screen in CellMedia PR123	Annex II List B	-
rr Cell antibody screen in CellStab PR106	Annex II List B	-
r'r and r'r Cell antibody screen in CellStab PR107	Annex II List B	-
rr Cell antibody screen in CellMedia PR108	Annex II List B	-
r'r and r'r Cell antibody screen in CellMedia PR109	Annex II List B	-
IgG coated cells PR092	Annex II List B	-
3 Cell antibody screen papainised in Alsevers PR124	Annex II List B	-
AB Serum PN061	Annex II List B	-
ID Panel 1 in Alsevers PR144	Annex II List B	-
ID Panel 2 in Alsevers PR141	Annex II List B	-
ID Panel 1 in CellStab PR143	Annex II List B	-
ID Panel 2 in CellStab PR142	Annex II List B	-
ID Panel 1 in CellMedia PR163	Annex II List B	-
ID Panel 2 in CellMedia PR162	Annex II List B	-
ID Panel 1 in LISP PR146	Annex II List B	-
Papainised ID Panel 1 in Alsevers PR154	Annex II List B	-
Papainised ID Panel 1 in CellStab PR153	Annex II List B	-
Papainised ID Panel 2 in CellStab PR152	Annex II List B	-
Papainised ID Panel 1 in CellMedia PR173	Annex II List B	-
Papainised ID Panel 2 in CellMedia PR172	Annex II List B	-
Weak Anti-K Control PN043	Annex II List B	-
Weak Anti-c Control PN042	Annex II List B	-
Weak Anti-Fya Control PN044	Annex II List B	-
Weak Anti-D Control PN046	Annex II List B	-
Reference Panel 1 in Alsevers PR201	Annex II List B	-
Reference Panel 1 in CellStab PR202	Annex II List B	-
Reference Panel 2 in Alsevers PR211	Annex II List B	-
Reference Panel 2 in CellStab PR212	Annex II List B	-