



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