



Blood and Transplant

NHSBT Reagents

CERTIFICATE OF CONFORMANCE

PRODUCT: Weak anti-D control

LOT NUMBER(S): N046 3128

EXPIRY: 2027.08.17

MANUFACTURE: This product complies with the requirements of Directive 98/79/EC, UK MDR2002 (as amended) and the recommendations contained in the current edition of 'Guidelines for the Blood Transfusion Services in the United Kingdom'.

PERFORMANCE: The Quality Control testing of this product confirms compliance with all applicable guidelines and regulations and that it meets all specified design and performance features.

The strength of this batch of weak anti-D control falls within the range 0.09 ± 0.01 IU/mL as determined by a quantification analyser with traceable calibration to the WHO International Standard Anti-D immunoglobulin preparation available on the market at the time of testing.

CERTIFICATION: It is certified that the above information is authentic and correct, the batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

AUTHORISED BY:

S. Wink

DATE:

12 Sep 2025

On behalf of Reagents Management Team

NHSBT Reagents is ISO13485 certified and is registered to manufacture CE/UKCA marked *In Vitro* Diagnostic Devices

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