NHSBT Reagents,
14 Estuary Banks, Speke, Liverpool, L24 8RB,
Great Britain
Telephone: +44 (0)151 268 7157
Email: reagents@nhsbt.nhs.uk
www.blood.co.uk/reagents

Product Code	Product Name	UDI-DI
PN062	AB Serum for use in Antibody Quantification	5055232400475

Amendments from the previous version of these instructions for use in purple text.

Intended Use

For professional use as an IVD device as a constituent of the cell cocktail used for quantification of anti-D and anti-c antibodies.

Principles of the examination method

AB serum for use in antibody quantification is added to a cocktail of Bovine Serum Albumin (BSA), Papainised cells and Phosphate Buffered Saline (PBS) and used to test against standard anti-D and anti-c dilutions to prepare a calibration curve. Diluted patient samples are tested against these cells and the level of antibody is calculated using the standard calibration curve. These products are for use in automated immunohematology quantification methods.

Components

This reagent is provided as AB serum which has been sterile filtered and contains sodium azide as a bacteriostat at less than 0.1%.
This reagent has been prepared from a pool of human AB serum or defibrinated plasma.
The device is filled into 500 mL HDPE bottles which are sealed with a cap.

Special materials and equipment required but not supplied

Calibrated volumetric pipettes.
Centrifuge or cell washer.
Quantification equipment and consumables.
Dilution equipment and consumables.
Phosphate Buffered Saline Solution (PBSS).
30% Bovine Serum Albumin.

Reagent preparation

Centrifuge before use.
Use reagent as supplied, for use as a constituent of the cell cocktail for quantification of anti-D and anti-c antibodies.

Storage and shelf life after opening

Store at 2-8ºC.
Once opened the device can be used until stated expiry date.
Do not use beyond the expiry date.
Immediately after use, the bottle must be capped and placed in the correct storage temperature.

Warnings and precautions

The donations used in this product are of human origin. They have been tested and found negative for the mandatory microbiological tests required by the UK Guidelines for Blood Transfusion Services during donation testing. No known test methods can offer assurances that products derived from human blood will not transmit infectious diseases. This device should be handled as clinical material. The device and any contaminated packaging should be disposed of in accordance with local, state, or national legislation.

For healthcare professional use only.

The reagent should not be used if turbid or discoloured.

This device is not provided sterile.

Do not use if the reagent bottle is cracked or leaking.

Recommended procedure

To prepare a 20% cell cocktail mix:

- 10 mL 30% BSA.
- 5 mL AB serum.
- 15 mL PBS.
- 20 mL of a 50% cell suspension (OR1R1 cells for anti-D quantification and O rr cells for anti-c quantification with PBSS).

Control procedure

Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory standards. If controls set up with the batch of tests fail to give required results, then all tests must be repeated. Where possible, each sample should be tested in parallel with the previous sample and the results compared to identify significant changes in antibody concentration.

Interpretation of results

This device does not produce results; it is a constituent of the cell cocktail used in antibody quantification.

Performance characteristics

This device is an inert serum for use in the cell cocktail used in antibody quantification. It has been prepared from a pool of human AB serum or defibrinated plasma and screened to ensure the absence of antibodies to major blood group antigens and rouleaux inducing properties at ambient temperature, at 37ºC papain techniques, by LISS tube and Bio-Rad gel antiglobulin techniques. The device is used in cell diluent in antibody quantification of anti-D and anti-c antibodies and has been screened on an antibody quantification analyser to ensure its suitability for purpose.

Limitations of the examination procedure

Exogenous interference is possible from therapeutic immunoglobulin including but not limited to anti-D prophylaxis and IVIg.

False positive or false negative results may occur due to contamination of test material, improper storage, incubation time or temperature, improper or excessive centrifugation or deviation from the recommended technique.

Visual evidence of hyperlipidaemia or haemolysis and age of specimen may affect the interpretation of test results.

Suitability for use in other techniques must be validated by user.

Literature references

Directive 98/79/EC on In vitro diagnostic medical devices.
Guidelines for the Blood Transfusion Services in the UK.
British Society for Haematology Guidelines for Blood Grouping and Antibody Testing in Pregnancy.

Note – Any serious incident that has occurred in relation to AB Serum for Quantification should be reported to the manufacturer and the competent authority in which the user and/or the patient is established.

EC REP
Quality First International OÜ, Laki 30,12915 Tallinn, Estonia

Symbols used on NHSBT Reagents labels

Note - not all symbols listed are applicable for this product - please refer to product labels.

Detail	Label details
Batch code symbol	LOT
Use by date symbol	
Expiry date format	YYYY.MM.DD
In Vitro Diagnostic medical device symbol	IVD
Instructions for use symbol (with website - electronic IFU)	 blood.co.uk/reagents
Negative control symbol	CONTROL –
Positive control symbol	CONTROL +
EC Rep symbol	EC REP

Detail	Label details
2-8°C temperature range symbol	
Below -20°C symbol	
CE Mark symbol	CE
UKCA symbol	UK CA
Manufacturer's symbol	
Keep Away from Sunlight symbol	
Contains human blood or plasma derivatives symbol	
Unique Device Identifier symbol	UDI

Lot number Format

NHBST Reagents product lot numbers are in the following format:

NAAA MXXX or RAAA MXXX

N Non-Red cell or R Red cell

AAA Product identifier from product code

M Reagent Manufacturing Unit - main batch = 3
And sub-batch identifier - 4, 5, 6 .... etc. for sub batch

XXX Lot number