CE 1434 IVD

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Product Code	Product Name	UDI-DI
PN061	AB Serum	5055232400376

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

Intended use
For professional use as an IVD device as a negative control for use in antibody detection techniques. This reagent can be used to give qualitative data to assure the effectiveness of each batch of laboratory tests.

Principles of the examination method
AB serum is incubated with red blood cells in an immunohaematology test system to show when testing unknown samples by direct or indirect methods that the system is working.
This product can be used for as a negative control in standard antiglobulin, and enzyme techniques.

Components
This reagent is prepared from a pool of group AB human serum or defibrinated plasma which has been sterile filtered and contains sodium azide as a bacteriostat at less than 0.1%.
The product is supplied in 10 mL volume, to be used directly from the vial.

Special materials and equipment required but not supplied
Calibrated volumetric pipettes.
Where applicable:

- Bio-Rad ID-System, Grifols DG Gel System or ORTHO ID-MTS consumables and equipment.
- Tube centrifuge or cell washer.
- Phosphate Buffered Saline Solution (PBSS).
- Anti-Human Globulin reagent.
- Water bath or dry heat incubators.

Reagent preparation
Allow to reach required temperature for test to be performed.
Use reagent as supplied.

Storage and shelf life after opening
Store at 2-8ºC.
Once opened the device can be used until the stated expiry date.
Do not use beyond the expiry date.
Protect from contamination.
Immediately after use, the vial must be capped and placed, upright, at 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 in accordance with local, state or national legislation.

For healthcare professional use only.

The recommended conditions of storage and use must be rigidly applied.

The reagent should not be used if cloudy or opaque.

If a precipitate, gel or particles are present the reagent should be centrifuged before use.

This reagent should not be used in automated antibody quantitation systems.

This device is not provided sterile.

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

Examination procedure

This AB serum can be used as a negative control in standard antiglobulin, and enzyme techniques as described in the current Guidelines for the Blood Transfusion Services in the UK and in current British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories. The precise conditions for red cell suspension, ratio, incubation, and reading must be identical to those of the batch of tests being controlled.

Interpretation of results

AB serum contains no antibodies and therefore should give a negative reaction. The presence of agglutination indicates a positive reaction, and the control has failed. Failure to obtain a negative result must be investigated and any associated batch of tests repeated.

Performance characteristics

AB Serum is 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 gel antiglobulin techniques.

The absence of other blood group antibodies has been assured using a panel of red cells which bear the following antigens: C, D, E, c, e, Le^a, Le^b, K, Kp^a, P1, C^w, M, N, S, s, Lu^a, Jk^a, Jk^b, Fy^a and Fy^b.

Negative reactions with this panel also exclude the presence of antibodies to antigens having a prevalence of greater than 99%.

Antibodies to low incidence blood group antigens may occur as contaminants and may, on rare occasions, give rise to false positive results.

Limitations of the examination procedure

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

False positive results may occur due to contamination of test material, improper storage, incubation time or temperature or improper or excessive centrifugation.

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 Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories.

Note – Any serious incident that has occurred in relation to AB serum 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	
UKCA symbol	
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