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IVD

Product Code	Product Name	UDI-DI	Registration
PR092	IgG Coated Cells	05055232400024	CE 1434 UKCA 0843

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 qualitative control to assure that the anti-IgG activity in negative antiglobulin tests has not been fully or partially neutralised. IgG coated red cells are added to negative tests. IgG coated cells can also be used to monitor the washing efficiency of cell-washing centrifuges.

Principles of the examination method
Sera/plasma samples are incubated with reagent red cells to determine the presence or absence of agglutination by indirect immunohaematological methods. IgG coated cells are used to assure that no free IgG is left behind during the washing phase of IAT immunohaematological methods which neutralises the AHG (anti-IgG) when added to the tube. The cells are sensitised with an IgG antibody that will react and agglutinate with Anti-Human Globulin (AHG) if the cells have been washed correctly. Controlling and ensuring testing and equipment is working as expected allows determination of safe and compatible transfusions for potential recipients. This product is used in manual methods.

Components
These reagent red cells, prepared from non-remunerated blood donors are leucodepleted, washed and suspended in a preservative solution.
The product is supplied as a 4% ± 0.2% suspension in Alsevers of human red cells coated with IgG (anti-D) in sufficient quantity to comply with UK Guidelines relating to reaction strength when tested with anti-IgG.
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.
Tube centrifuge or cell washer.

Reagent Preparation
Allow to reach required temperature for test to be performed, mix before use.

Storage and shelf life after first 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 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.
Cells must not be pooled.
Do not use if red cells appear contaminated, discoloured or haemolysed.
This device is not provided sterile.
Do not use if the reagent vial is cracked or leaking.

Some loss of reactivity may occur during the stated shelf life. Since this loss cannot be predicted or controlled and is partly determined by the characteristics of individual blood donations or donors, the recommended conditions of storage and use must be rigidly applied.

Examination procedures

Control of negative antiglobulin tests
1. Add 1 drop of IgG coated cells to each negative antiglobulin test and mix.
2. Centrifuge all tubes for 20 seconds at 1000 rcf or a suitable time and force.
3. Gently resuspend red cell button and read macroscopically for agglutination.

Interpretation of results
The IgG coated cells should give a macroscopic reaction with negative antiglobulin tests, when used as recommended.
A macroscopic reaction (grade 2-3) indicates the anti-human globulin has not been neutralised.
All tests with IgG coated cells giving a negative or equivocal result must be considered invalid and the AHG test repeated.

Monitoring efficiency of cell-washing centrifuges
1. Use one tube for each place in the centrifuge head and add to each 1 volume of the IgG coated cells plus 2 volumes of AB serum.
2. Run the centrifuge through its normal cycle of 3 or 4 washes.
3. Add anti-human globulin reagent as per manufacturer's instructions and mix.
4. Centrifuge all tubes for 20 seconds at 1000 rcf or a suitable time and force.
5. Gently resuspend red cell button and read macroscopically for agglutination.

Interpretation of results
All tubes should show equal strength 2+ reactions or greater. Failure to do so indicates that the centrifuge is not washing correctly and should be taken out of service until the problem is corrected.

Performance characteristics
In both procedures an unequivocal 2-3 grade viewed macroscopically should be regarded as proof that test mechanism was working or that the centrifuge washing cycle was adequate for AHG test to work effectively.

Limitations of the examination procedure
If tests set up to control the batch of tests fail to give required results all tests must be repeated.

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.

Literature references

The requirements of 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 IgG Coated Cells 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