CE 1434 IVD

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Product Code	Product Name	UDI-DI
PN042	Weak anti-c control	5055232400390
PN043	Weak anti-K control	5055232400383
PN044	Weak anti-Fya control	5055232400406
PN046	Weak anti-D control	5055232400413

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

Intended use
For professional use as an IVD device for the control of antibody detection techniques using indirect antiglobulin methods. This reagent can be used to provide qualitative data to assure the effectiveness of each batch of laboratory tests designed to detect red cell antibodies.

Principles of the examination method
Weak antisera controls are incubated with red blood cells known to exhibit the appropriate antigen in an immunohaematological test system to show that the system can detect an antibody/antigen reaction when testing unknown samples. Ensuring that the system is working correctly allows determination of safe and compatible transfusions for potential recipients. These products can be used for manual or automated methods.

Components
These reagents are prepared from human sera/plasma containing the relevant red cell antibody at a strength to meet the requirements of the Guidelines for the Blood Transfusion Services in the UK. Weak anti-D (PN046) is prepared with a value of 0.09 IU/mL ± 0.01.
The antibody containing sera/plasma is diluted using a diluent containing 3% v/v bovine serum albumin (containing EDTA and sodium azide), from a BSE free source, and Phosphate Buffered Saline Solution.
They are 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 or ORTHO BioVue consumables and equipment,
- Tube centrifuge or Cell Washer,
- Phosphate Buffered Saline Solution,
- 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 2º- 8ºC.

Once opened the device can be used until the stated expiry date.
Do not use beyond the expiry date.
Immediately after use, the vial must be capped and placed back, 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.
These reagents are not suitable for antigen typing of red cells.
For healthcare professional use only.
These reagents have not been absorbed to remove ABO alloagglutinins.
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.
When used in accordance with the Instructions for Use and Good Laboratory Practices there is limited potential for carryover.
Do not use if the reagent vial is cracked or leaking.
This device is not provided sterile.

Examination procedure

Weak antisera controls have been validated as an IAT control in Bio-Rad and Grifols gel cards, Ortho Biovue cassettes and LISS Tube IAT. Suitability for use in other techniques must be validated by the user. 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

The presence of agglutination indicates a positive result. Weak antisera controls must give an unequivocal positive reaction when tested with cells that have homozygous expression of the target antigen. The strength of reaction should be graded in accordance with user laboratory protocol.
Failure to obtain an unequivocal positive reaction against homozygous antigen positive cells (i.e. anti-c vs rr, anti-K vs K+k-, anti-Fya vs Fy(a+b-), anti-D vs R1R1) must be investigated and any associated batch of tests repeated.

Performance characteristics

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, P_1, C^w, M, N, S, s, Lu^a, Jk^a, Jk^b, Fy^a, 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.
Weak anti-D (PN046) may contain weak anti-C and/or E which may be active in systems using enzyme treated cells.

Limitations of the examination procedure

Heterozygous cells may give weaker or occasionally negative reactions against weak antisera controls.

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

Literature references

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 Weak antisera controls 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