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IVD

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Product Code	Product Name	UDI-DI
PR012	A1rr in Alsevers	5055232400031
PR014	A1rr in CellStab	5055232400079
PR015	A1rr in CellMedia	5055232400086
PR022	A2rr in Alsevers	5055232400048
PR033	Brr in Alsevers	5055232400055
PR034	BR1r in Alsevers	5055232400116
PR035	Brr in CellStab	5055232400093
PR036	Brr in CellMedia	5055232400109
PR044	OR1r in Alsevers	5055232400062
PR045	OR1r in CellStab	5055232400123
PR046	OR1r in CellMedia	5055232400130

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

Intended use
For professional use as an IVD device used to qualitatively determine the presence of antibodies to ABO antigens found in human sera/plasma samples. They are also intended for use in quality control of ABO and Rh (D) grouping tests in patients.
Reagent red cells suspended in Alsevers are intended for tube use.
Reagent red cells suspended in CellStab are intended for use in Bio-Rad ID-System Gel Cards.
Reagent red cells suspended in CellMedia are intended for use in Grifols DG Gel Cards.

Principles of the examination method
Plasma/sera samples are incubated with reagent red cells to determine the presence or absence of agglutinins by direct immunohaematological methods.
The ABO type of a patient or donor is determined by testing their red cells with anti-A and anti-B to detect the presence of the A and B antigens and testing their plasma or serum with A and B cells to detect the presence of anti-A and anti-B, allowing determination of safe and compatible transfusions for potential recipients. These products can be used for manual or automated methods.

Components
These reagents include A1rr, A2rr, Brr, OR1r and BR1r cells which may be manufactured from pooled cells.
These reagent red cells, prepared from non-remunerated donor blood, are leucodepleted, washed and suspended in a preservative solution.
These reagent red cells are supplied as:

- 2.8 ± 0.2% suspension in Alsevers preservative.
- 0.8 ± 0.2% suspension in Bio-Rad CellStab.
- 0.8 ± 0.2% suspension in Grifols CellMedia.

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 or Grifols DG Gel System 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, 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, 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 in accordance with local, state or national legislation.
For healthcare professional use only.
Cells must not be pooled by user.
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 antigenic expression 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.

Primary sample collection, handling and storage

Use clotted serum or EDTA plasma samples according to current edition of the British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories.

Examination Procedure

Reverse Group

Tube centrifugation (spin) method for PR012, PR022, PR033, PR034, PR044:

1. Add cells to test serum/plasma in 1:1 ratio.
2. Mix, incubate at room temperature for 5 minutes then centrifuge all tubes for 20 seconds at 1000 rcf or a suitable time and force.
3. Gently resuspend red cell button and read macroscopically.

Gel Card Technologies PR014, PR015, PR035, PR036, PR045, PR046:
For method of use as control with Bio-Rad and Grifols ABO/Rh blood grouping cards – refer to the Instructions for Use of the cards being used. NHSBT Reagents ABO cells in CellStab and CellMedia can be used in place of the Bio-Rad DiaCell and DG Gel System reagents.

Quality control of ABO and RhD grouping tests

Refer to manufacturer's instructions for use for phenotyping reagent used

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, all tests must be repeated.

Interpretation of results

The strength of reaction should be graded in accordance with user laboratory protocols. The results should be interpreted as indicated in British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories. If anomalous ABO results are found, the grouping should be repeated and include both O cells and auto controls.

Performance characteristics

The antigen status of the cells is confirmed by an established third-party device in line with Commission Decision 2009/886/EC (Common Technical Specifications for In Vitro Diagnostic Medical Devices).
To confirm the antigen status, and rule out cross-reactivity, each cell is tested against 2 examples of phenotyping antisera for each specificity.
Antigen strength is tested by presence or absence of antigens described by allelic genes.
Typical antigen expression is confirmed by flow cytometry for RhD antigens.

Limitations of the examination procedure

When used for reverse ABO grouping exogenous interference is possible from (list is not exhaustive):

- therapeutic immunoglobulins including but not limited to: IVIg, anti-CD38 (rare), anti-CD47,

When used for reverse ABO grouping endogenous interference is possible from (list is not exhaustive):

- patients with antibodies reacting <25^{o}C e.g., anti-M, anti-P1, cold autoantibodies.

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. If these reagent red cells are used in a proprietary system, the manufacturer's recommended method must be followed.
Visual evidence of hyperlipidaemia or haemolysis and age of specimen may affect the interpretation of test results.

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.
Decision 2009/886/EC Amending Decision 2002/364/EC on Common Technical Specifications for In Vitro Diagnostic Medical Devices.

Note – Any serious incident that has occurred in relation to ABO 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