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IVD

Product Code	Product Name	UDI-DI	
PR101	2 cell antibody screening set in Alsevers	05055232400147	 1434  0843
PR102	2 cell antibody screening set in CellStab	05055232400154	
PR103	2 cell antibody screening set in CellMedia	05055232400161	
PR121	3 cell antibody screening set in Alsevers	05055232400178	
PR122	3 cell antibody screening set in CellStab	05055232400185	
PR123	3 cell antibody screening set in CellMedia	05055232400192	

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

Intended use

For professional use as an IVD device to give qualitative data to determine whether patient sera/plasma samples contain irregular antibodies to red cell antigens.

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.

Reagent red cells suspended in Alsevers are intended for tube use.

Principles of the examination method

Patient or donor sera/plasma samples are incubated with reagent red cells to determine the presence or absence of agglutination by indirect immunohaematological methods. Antibody detection allows determination of safe and compatible transfusions for potential recipients. These products can be used for manual or automated methods.

Components

Antibody screening sets consist of 2 or 3 cells, each cell is differentiated by a number 1 and 2 or 1-3.

These reagent red cells, prepared from non-remunerated blood donors, are leucodepleted, washed and suspended in a preservative.

These cells are supplied as:

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

They are supplied in 10 mL volumes, 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 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 2-8°C.

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 back, 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 for its use. 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 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

Indirect Antiglobulin Test (IAT) Tube method for PR101 and PR121:

1. Add 2 volumes of test sera/plasma to a labelled tube.
2. Add 1 volume of product.
3. Mix thoroughly and incubate at 37°C for 45 minutes.
4. Wash cells at least three times.
5. Add Anti-Human Globulin reagent as per manufacturer's instructions.
6. Centrifuge all tubes for 20 seconds at 1000 rcf or a suitable time and force.
7. Gently resuspend red cell button and read macroscopically for agglutination.
8. Confirm validity of all negative tests with IgG sensitised cells.

Gel Card technologies PR102, PR103, PR122 and PR123:

For method of use in Bio-Rad ID system or DG Gel System refer to the instructions for use of the cards being used. NHSBT Reagents Screening Cells in CellStab and CellMedia can be used in place of the ID-DiaCell or DG Gel System reagents.

Control procedure

Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations. If controls set up with the batch of tests fail to give required results, then all tests must be repeated.

Interpretation of results

The presence and absence of agglutination should be used to determine the presence of any antibodies in accordance with British Society for Haematology Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories. The strength of reaction should be graded in accordance with user laboratory protocol. A batch specific product profile is provided which states the antigen status of each cell.

Performance characteristics

To confirm the antigen profile, and rule out cross-reactivity, each screening 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 D, Fy^a and Fy^b. Additional flow cytometry testing is performed to determine the expression of HLA antigens. No donations with a high expression of HLA antigens are used in the manufacture of screening cells.

Screening cells react with undiluted weak antisera controls, anti-D (less than or equal to 0.1 IU/mL), anti-c, anti-K, anti-Fy^a. Cells homozygous for the relevant antigen give an unequivocal positive reaction.

Blood group antibodies (i.e. anti-A and anti-B) other than the target are not detected when tested against group O plasma.

The designation of positive or negative status for a particular antigen relates to the normal expression of that antigen, if an individual cell is known to possess a weak or variant form of an antigen, this is indicated on the profile.

Limitations of the examination procedure

Exogenous interference is possible from therapeutic immunoglobulin including but not limited to anti-D prophylaxis, IVIg, anti-CD38, anti-CD47.

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.

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 Antibody Screening Cells should be reported to the manufacturer and the competent authority in which the user and/or the patient is established.

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 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	
Use by date symbol	
Expiry date format	YYYY.MM.DD
In Vitro Diagnostic medical device symbol	
Instructions for use symbol (With website - electronic IFU)	 blood.co.uk/reagents
Negative control symbol	
Positive control symbol	
EC Rep symbol	

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	

Lot number Format

NHBT 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