

INF103/4.1 – Instructions for Use – Reference Panels



Blood and Transplant

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Product Code	Product Name	UDI-DI	Registration	
PR201	Reference panel 1 in Alsevers	05055232400543		
PR202	Reference panel 1 in CellStab	05055232400550		
PR211	Reference panel 2 in Alsevers	05055232400567		
PR212	Reference panel 2 in CellStab	05055232400574		

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

Intended Use

For professional use as IVD devices to give qualitative data to aid with identifying the specificity of antibodies to red cell antigens in human sera/plasma. The device products are not intended for routine antibody identification, but only for use in reference laboratories who often receive samples with more than one specificity. These special variations are intended for use in patients with anti-c (Panel 1) or anti-e (Panel 2) who also have additional antibodies.

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.

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 direct and/or indirect immunohaematological methods. Antibody identification allows determination of safe and compatible transfusions for potential recipients. These products can be used for manual or automated methods.

Components

Reference panels consist of 10 cells, each cell is differentiated by a number 1-10.

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

These cells are supplied as:

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

They are supplied in 3 mL volume, to be used directly from the vial.

Equipment required but not supplied

Calibrated volumetric pipettes.

Where applicable:

- Bio-Rad ID-System consumables and equipment.

Controlled if copy number stated on document and issued by QA

(Template Version 03/02/2020)

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- 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 the 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 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 PR201 and PR211:

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.

Direct agglutination Tube method for PR201 and PR211:

1. Add equal volumes of test sera/plasma and product to a labelled tube.
2. Mix thoroughly and incubate at required temperature (4°C / Room Temperature / 37°C) for required time (15-60 minutes).
3. Centrifuge all tubes for 20 seconds at 1000 rcf or a suitable time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination.

Gel Card technologies PR202 and PR212

For method of use in Bio-Rad ID refer to the instructions for use of the cards being used. NHSBT Reagents Reference Panels in CellStab can be used in place of ID-DiaPanel reagents for patients with anti-c (Panel 1) or anti-e (Panel 2) who also have additional antibodies.

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, then all tests must be repeated.

Interpretation of results

The presence and absence of agglutination should be recorded on the Panel profile specific to the batch of Reference Panel. The strength of reaction should be graded in accordance with user laboratory protocol. The pattern of reactivity should be used to determine the identity of any antibodies present in accordance with British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories. It may not be possible to identify all antibodies in patients with multiple antibodies or antibodies to high frequency antigens with a single panel.

Performance characteristics

To confirm the antigen profile, and rule out cross-reactivity, each panel cell is tested against 2 examples of phenotyping antisera for each specificity.

Antigen strength is tested by the 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. Due to the complexity of finding suitable panel cells, HLA positive donations may be used dependent on the red cell antigen profile required. These caveats are applied:

- The product profile informs the user of the HLA positive status.
- No more than two HLA positive donations are used in any single panel.

Reference panel 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 (where the antigen is expressed). 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 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 Reference Panel 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	Detail	Label details
Batch code symbol		2-8°C temperature range symbol	
Use by date symbol		Below -20°C symbol	
Expiry date format	YYYY.MM.DD	CE Mark symbol	
In Vitro Diagnostic medical device symbol		UKCA symbol	
Instructions for use symbol (With website - electronic IFU)	 blood.co.uk/reagents	Manufacturer's symbol	
Negative control symbol		Keep Away from Sunlight symbol	
Positive control symbol		Contains human blood or plasma derivatives symbol	
EC Rep symbol		Unique Device Identifier symbol	

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