CE 1434 IVD

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Product Code	Product Name	UDI-DI
PR141	ID Panel 2 in Alsevers	5055232400260
PR142	ID Panel 2 in CellStab	5055232400284
PR143	ID Panel 1 in CellStab	5055232400277
PR144	ID Panel 1 in Alsevers	5055232400253
PR146	ID Panel 1 in LISP	5055232400314
PR152	Papainised ID Panel 2 in CellStab	5055232400345
PR153	Papainised ID Panel 1 in CellStab	5055232400338
PR154	Papainised ID Panel 1 in Alsevers	5055232400321
PR162	ID Panel 2 in CellMedia	5055232400307
PR163	ID Panel 1 in CellMedia	5055232400291
PR172	Papainised ID Panel 2 in CellMedia	5055232400369
PR173	Papainised ID Panel 1 in CellMedia	5055232400352

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 aid with identifying the specificity of antibodies to red cell antigens in human sera/plasma samples.
Reagent red cells suspended in Alsevers are intended for tube use.
Reagent red cells suspended in LISP 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
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
ID 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 Preservative.
- 1.5 ± 0.2% suspension in Low Ionic Strength Preservative (LISP).
- 0.8 ± 0.2% suspension in Bio-Rad CellStab.
- 0.8 ± 0.2% suspension in Grifols CellMedia.

They are supplied in 5 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 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 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 treated 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 procedures
Indirect Antiglobulin Test (IAT) Tube method for PR141, PR144, PR154, PR146:

1. Add 2 volumes of test sera/plasma to a labelled tube (1 volume for LISP PR146).
2. Add 1 volume of product.
3. Mix thoroughly and incubate at 37°C for 45 minutes (15 minutes for LISP PR146).
4. Wash cells at least three times in PBSS.
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 PR141, PR144, PR154, PR146:

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 PR142, PR143, PR152, PR153, PR163, PR173:
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 ID panels in CellStab and CellMedia can be used in place of the ID-DiaPanel 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 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 ID 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 Standards for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories. The following antigens will be absent or reduced in papain treated red cells: M, N, S, s, Fy^a, Fy^b. 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 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.

ID 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 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 ID Panel 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.