CE 1434 IVD

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Product Code	Product Name	UDI-DI
PR106	rr Antibody Screen in CellStab	5055232400215
PR107	r'r/r''r Antibody Screen CellStab	5055232400222
PR108	rr Antibody Screen in CellMedia	5055232400239
PR109	r'r/r"r Antibody Screen in CellMedia	5055232400246

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 if antenatal patients, who have received prophylactic anti-D, have any other irregular red cell antibodies. These cells are not intended for routine antibody screening.
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 sera/plasma samples are incubated with reagent red cells to determine the presence or absence of agglutination by indirect immunohaematological methods. Identifying other irregular antibodies aids in the diagnosis and management of haemolytic disease of the foetus and neonate (HDFN). These products can be used for manual or automated methods.

Components
rr screening cells consist of 2 sets of 2 cells, each cell is differentiated by a number 1-4. Set 1 (cells 1 and 2) can be used as a screening set but set 2 (cells 3 and 4) is a sub-set and must always be used in conjunction with cells 1 and 2.
These cells are supplied as a 0.8 ± 0.2% suspension in Bio-Rad CellStab or Grifols CellMedia.
These reagent red cells, prepared from non-remunerated blood donors, are leucodepleted, washed and suspended in a preservative 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 or Grifols DG consumables and equipment.

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, 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.
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.

This screening set must not be used for general antibody screening. This screening cell set is intended for use with patients who have received prophylactic anti-D as part of their antenatal care.

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
Gel Card technologies.
For method of use in Bio-Rad ID system or Grifols 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 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 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 protocols. 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 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 rr screening cells.

Screening cells react with undiluted weak antisera controls, 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 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 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.
British Society for Haematology Guidelines for Blood Grouping and Antibody Testing in Pregnancy.

Note – Any serious incident that has occurred in relation to rr Screening 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