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Product Code	Product Name	UDI-DI
PR408	Papainised Quantification cells - OR1R1	5055232400529
PR409	Papainised Quantification cells - Orr	5055232400536

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

Intended use
For professional use as an in vitro diagnostic device used in the quantification of anti-D and anti-c. This device is intended to be used as a quantitative aid in the diagnosis and management of haemolytic disease of the foetus and neonate (HDFN).

Principles of examination methods
The papainised cells are added to a cocktail of Bovine Serum Albumin (BSA), AB serum and Phosphate Buffered Saline Solution (PBSS) and used to test against standard Anti-D and Anti-c dilutions to prepare a calibration curve. Diluted patient samples are tested against these cells and the level of antibody is calculated using the standard calibration curve. These products are for use in automated immunohaematology quantification methods. This product is used as a quantitative aid in the diagnosis and management of haemolytic disease of the foetus and neonate (HDFN).

Components
These reagent red cells, prepared from non-remunerated donors, are leucodepleted, washed and suspended in a preservative solution.
Cells of the same relevant phenotype may be pooled during processing.
The papain treated cells are supplied as a 25 ± 2% suspension in modified Alsevers solution.
They are supplied in 25 mL volumes.

Special materials and equipment required but not supplied
Calibrated volumetric pipettes.
Centrifuge or cell washer.
Quantification equipment and consumables.
Dilution equipment and consumables.
Phosphate Buffered Saline Solution (PBSS).
AB serum.
30% Bovine Serum Albumin.

Reagent preparation
Wash papainised cells in PBS until supernatant is clear.
Prepare cells as described in local validated procedures.

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.

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.
Do not use if red cells appear contaminated, discoloured, or excessively haemolysed which cannot be resolved by washing in PBSS.
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.

Recommended procedure

Add prepared cells into cell cocktail to be used for quantification of anti-D or Anti-c as described in local validated procedures
To prepare a 20% cell cocktail mix:

- 10 mL 30% BSA.
- 5 mL AB serum.
- 15 mL PBS.
- 20 mL of a 50% cell suspension (OR1R1 cells for anti-D quantification and O rr cells for anti-c quantification with PBSS).

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. Where possible, each sample should be tested in parallel with the previous sample and the results compared to identify significant changes in antibody concentration.

Interpretation of results

This reagent is used to test against standard Anti-D and Anti-c dilutions to prepare a calibration curve. Diluted patient samples are tested against this reagent and the level of antibody is calculated using the standard calibration curve.

Performance characteristics

The reagent red cells selected are group O C^w negative and K negative, one cell is R1R1, and one is rr.
The cells are phenotyped using anti-D, anti-C^w, anti-C, anti-E, anti-c, anti-e and anti-K to comply with the specifications outlined in the Guidelines for the Blood Transfusion Services

in the UK. The antigenic status of these red cells has been determined using, wherever possible, at least two examples of phenotyping antisera directed against that antigen.

Limitations of the examination procedure

Exogenous interference is possible from IVIg and other enzyme reactive antibodies (non-D, non-c, e.g., autoantibodies, anti-G).
R1R1 cells will react with prophylactic anti-D by quantification. Attempts to distinguish between prophylactic and immune anti-D must be made in accordance with user policy.
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

Guidelines for the Blood Transfusion Services in the United Kingdom.
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.
The Medical Devices Regulations 2002 (UK Statutory Instruments 2002 No. 618), as amended.

Note – Any serious incident that has occurred in relation to Papainised Cells for Quantification should be reported to the manufacturer and the competent authority in which the user and/or the patient is established.

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