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Product Code	Product Name	UDI-DI	Registration	
PR407	Titration cells In CellStab	5055232400000	UKCA	CE
PR406	Titration Cells in CellMedia	5055232400659	UKCA	

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

Intended use
For professional use as an IVD device for use in antibody titration tests to provide semi-quantitative data to determine the relative strength of atypical blood group antibodies of potential clinical significance. It is intended that these cells are tested against selected dilutions of plasma from the patient with red cell antibodies, by gel card technique, in order to assist clinical decisions regarding the significance of the patient's antibody.
Reagent red cells suspended in CellStab are specifically for use on Bio-Rad Gel Cards.
Reagent red cells suspended in CellMedia are intended for use in Grifols DG Gel Cards.

Principles of the examination method
Plasma/sera samples are incubated with reagent red cells to determine the presence or absence of agglutination by immunohaematological methods. An indication of antibody strength allows determination of prognosis and treatment of patients. These products can be used for manual methods.

Components
Titration cells consist of 2 cells, each cell is differentiated by a number 1 and 2.
These reagent red cells, prepared from non-remunerated blood donors, are leucodepleted, washed and suspended in a preservative solution.
These cells are supplied as:

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

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.
- Phosphate Buffered Saline

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 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.

Primary sample collection, handling, and storage
Use clotted serum or EDTA plasma samples according to current version of the British Society for Haematology Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories.

Examination procedure
Refer to Bio-Rad ID system or Grifols DG Gel System instructions for use.
Test doubling dilutions (1 in 2, 1 in 4, etc) of plasma prepared in phosphate-buffered saline by IAT using reagent red cells, where possible, showing heterozygous expression of the corresponding antigen(s).

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 of agglutination indicates a positive result; the strength of reaction should be graded. The strength of reaction should be graded in accordance with user laboratory protocol. The titre or strength of an antibody is expressed as the reciprocal of the last dilution to give a positive result of a grade 1 or more. For antenatal testing, refer to the BSH Guideline for blood grouping and red cell antibody testing in pregnancy for interpretation of the results.

Performance characteristics
The reagent red cells selected for use as titration cells are negative for Wr^a.

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

Literature References
Directive 98/79/EC on In vitro diagnostic medical devices.
UK Medical Devices Regulations 2002 (as amended)
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 Titration 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