INF81/6 – Instructions for Use - Papainised Alloabsorption Cells

NHS Blood and Transplant
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Product Code	Product Name	UDI-DI
PR404	Papainised Alloabsorption OR1R1 and Orr cells	5055232400505
PR405	Papainised Alloabsorption OR2R2 cells	5055232400512

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 to remove antibodies from patient sera. This device is intended for use in manual serology methods, as an aid to diagnosis in combination with a qualitative antibody identification assay, for use on sera from patients with suspected alloantibodies to assist clinical decisions regarding the selection of units for blood transfusion.

Principles of examination methods
Specially selected sets of allogenic red cells (usually from pooled donations) are used to remove auto- and/or alloantibody from a patient's sera/plasma. Patient sera/plasma is incubated with red blood cells expressing selected antigens which absorb antibodies from the patient sera/plasma. Papanisation of the cells destroys some antigens ensuring that these antibodies are not absorbed. After absorption, plasma may be used in standard immunohaematology screening and/or antibody identification and crossmatch techniques, but it should be noted that the adsorption might result in a slight reduction in the serological activity of alloantibodies.

Components
Each cell is identified by Rh phenotype (R1R1, rr or R2R2).
These reagent red cells, prepared from non-remunerated donors, are leucodepleted, Papainised, washed and suspended as a 30 ± 2% suspension in Modified Alsevers Solution.
Cells of the same relevant phenotype may be pooled during processing.
They are supplied in 20 mL volume, to be used directly from the vial.

Special materials and equipment required but not supplied
- Calibrated volumetric pipettes.
- Tube centrifuge or cell washer.
- Phosphate Buffered Saline Solution (PBSS).
- 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 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.

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 in the stated shelf life. Since this loss cannot be predicted or controlled and is partly determined by the characteristics of individual blood donations and donors, the recommended conditions of storage and use must be rigidly applied.

Absorption may result in a slight reduction in the serological activity of alloantibodies.

The following antigens will be absent or reduced in papain treated red cells: M, N, S, s, Fy^a, Fy^b therefore, antibodies to these antigens will not be absorbed from the patient's sera/plasma.

Primary sample collection, handling and storage

Clotted serum or EDTA plasma samples may be used, according to current edition of the British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories.

Examination procedure

1. Mix container by inversion and transfer 4mL cells into a labelled tube.
2. Centrifuge at 2500 rcf for 5 minutes (or equivalent speed and time) and remove supernatant and add PBSS.
3. Repeat step 2 twice or until supernatant is clear.
4. Pack cells and add 1 mL packed cells to labelled tubes.
5. Add up to 1 mL plasma/serum.
6. Mix and incubate at 37ºC for 10-15 minutes.
7. Centrifuge at 2000–3000 rcf for 2 minutes (or equivalent speed and time).
8. Test resulting plasma against selected cells as defined by laboratory protocols, including appropriate controls.

It is important to assess the specificity of all clinically significant red cell antibodies in patient serum/plasma to assist in clinical management of cases. Testing the treated patient serum/plasma against NHSBT Reagents cells by prescribed methods assists in this aim.

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 absorbed sera/plasma should be tested using standard immunohaematology screening and/or antibody identification and crossmatch techniques. The presence and absence of agglutination should be recorded. 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.

Performance characteristics

To confirm the antigen profile, and rule out cross-reactivity, each 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. 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 a variant form of an antigen, this is indicated on the profile.

Limitations of the examination procedure

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 UK.
British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories.
The Medical Devices Regulations 2002 (UK Statutory Instruments 2002 No. 618), as amended.

Note – Any serious incident that has occurred in relation to Papainised Alloabsorption Cells 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