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Product Code	Product Name	UDI-DI
PN221	0.2M DTT	5055232400499

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 accessory used to remove or denature certain red cell antigens which may assist in antibody identification tests. This device accessory is intended for use in manual serology methods as an aid to diagnosis in combination with a qualitative antibody identification assay.

Principles of the examination method
0.2 M Dithiothreitol (DTT) is incubated with patient/reagent red cells to remove or denature certain red cell antigens though a biochemical reaction. DTT treated red blood cells will not react with antibodies in the Kell blood group system nor with some examples of anti -Ge, - Lw^a, - Yt^a and some HTLA antibodies. This may be helpful in completing complex antibody investigations in immunohaematology laboratories as an aid in identifying some of the above antibodies and determine if underlying alloantibodies are present. Kx antigen is not denatured by DTT. 0.2 M DTT also removes CD38 from red cell surface so free anti-CD38 does not bind and agglutinate.

Components
The product is supplied frozen as 0.2 M solution of Dithiothreitol (DTT) in phosphate buffered saline pH 8.0, in 4 mL volumes, to be used directly from the vial.

Special materials and equipment required but not supplied
Calibrated volumetric pipettes.
Glass test tubes.
Phosphate Buffered Saline.
Tube centrifuge or cell washer.
Water bath or dry heat incubator.
Timer.

Reagent Preparation
Thaw before use.
Use the reagents as supplied.

Storage and shelf life after first opening
Store at -20°C or below.
Discard 24 hours after thawing.
Do not refreeze.
Do not use beyond the notified expiry date.

Warnings and precautions

For healthcare professional use only.

Storage at a temperature significantly above -20°C may result in acceleration in the rate of loss of reactivity of the reagent.

The device and any contaminated packaging should be disposed in accordance with local, state or national legislation.

The reagent should not be used if turbid or if there is evidence of precipitate, gel or particles present.

This device is not provided sterile.

Do not use if the reagent vial is cracked or leaking.

Primary sample collection, handling and storage

Red cells from specimens in EDTA may be used according to current addition of the British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories.

This reagent can also be used on reagent red cells.

Recommended technique

1. To one volume of washed packed red cells add four volumes of 0.2 M DTT.
2. Incubate at 37°C for 30 minutes. Mix every 5 minutes.
3. Wash cells 6 times in phosphate buffered saline pH 7.0.
4. Resuspend cells in phosphate buffered saline pH 7.0.
5. Test against appropriate antisera or patient's sera/plasma.

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. An example of a suitable control is to treat a k+ cell each time samples are treated and test against anti-k post treatment, a negative result should be obtained.

Interpretation of results

Human red cells treated with 0.2 M DTT should show no evidence of Kell system antigens. Removal of the antigens of one blood group system may allow identification of Kell system antibodies because reactions are no longer seen or determine if additional alloantibodies are present.

Performance characteristics

Each batch of 0.2 M DTT is tested to ensure that Kell system antigens are removed from the red cell surface of a cell known to have a specific Kell antigen when red cells are treated using the recommended examination procedure.

Limitations

Kx antigen is not denatured by DTT.

False positive or false negative results may occur due to contamination of test material, improper storage, improper incubation time or temperature, or deviation from the recommended technique.

Use of these reagents more than 24 hours after thawing may result in erroneous results.

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.
Branch DR, Muensch HA, Sy Siok Hian S, Petz LD. Disulphide bonds are a requirement for Kell and Cartwright blood group antigen integrity. Brit j Haem, 1983;54:573-8
Konigshaus GJ, Holland TI. The effect of dithiothreitiol on the LW antigen. Transfusion 1984;24:536-7.
The Medical Devices Regulations 2002 (UK Statutory Instruments 2002 No. 618), as amended.

Note – Any serious incident that has occurred in relation to 0.2 M DTT 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