NHSBT Reagents,
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Product Code	Product Name	UDI-DI
PN222	0.01 M DTT	05055232400482

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 denature human IgM antibodies 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
Patient sera/plasma is incubated with 0.01 M Dithiothreitol (DTT) which, at pH 7.3, denatures IgM antibodies though a biochemical reaction enabling differentiation between IgM and IgG antibodies. This may be helpful in completing complex serological antibody investigations in immunohaematology laboratories. This product is used in manual methods.

Components
This product is supplied frozen as 0.0 1M solution of Dithiothreitol (DTT) in phosphate buffered saline pH 7.3. It is supplied in 1 mL volume, to be used directly from the vial.

Special materials and equipment required but not supplied
Calibrated volumetric pipettes.
Glass test tubes.
Phosphate Buffered Saline Solution (PBSS) pH 7.
Tube centrifuge or cell washer.
Water bath or dry heat incubator.
Timer.

Reagent preparation
Thaw before use.
Use reagent 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 expiry date.

Warnings and precautions
This reagent is for healthcare professional use only.
Frozen storage at a temperature significantly above -20°C may result in an acceleration in the rate of loss of reactivity of the reagent.
The reagent should not be used if turbid or if there is evidence of precipitate, gel or particles present.
The device and any contaminated packaging should be disposed in accordance with local, state or national legislation.

This device is not provided sterile.
Do not use if the reagent vial is cracked or leaking.

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 technique
1. Dispense 1 volume of sera/plasma into each of 2 tubes.
2. Add 1 volume of 0.01 M DTT to tube 1.
3. Add 1 volume of PBSS pH 7 to tube 2.
4. Mix thoroughly.
5. Incubate at 37°C for 15 minutes.
6. Test the antibody activity in each sample against the appropriate red blood cells.

Control procedure
Control is included in examination procedure as a comparison test in PBSS. If controls set up with the test fails to give required results, then the tests must be repeated.

Interpretation of results
If the antibody is IgG, then activity in tubes 1 and 2 is positive and identical.
If the antibody is IgM, then activity in tube 1 is negative whilst 2 remains positive.
If there is a mixture of IgG and IgM, then activity in tube 1 will be still positive but weaker than tube 2.

Performance characteristics
Each batch of 0.01 M DTT is tested to ensure that IgM antibodies are denatured when sera/plasma is treated using the recommended examination procedure.

Limitations
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.

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.
Pirofsky B, Rosner ER. A new method to differentiate IgM and IgG red cell antibodies.
These reagents have been manufactured using methods as stated by W. John Judd in ‘Methods in Immunohaematology’ 1988.
The Medical Devices Regulations 2002 (UK Statutory Instruments 2002 No. 618), as amended.

Note – Any serious incident that has occurred in relation to 0.01 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	8°C 2°C
Below -20°C symbol	-20°C
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