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Product Code	Product Name	UDI-DI
PN161	ZZAP Kit (0.2M DTT & 1% Papain)	5055232400420

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 IgG antibodies from patient cells collected into EDTA. This device accessory is intended for use in manual serology methods as an aid to diagnosis in combination with a qualitative antibody identification assay for use on cells from patients with suspected autoantibodies.

Principles of the examination method:
ZZAP is a mixture of cysteine-activated papain and Dithiothreitol (DTT) which through a biochemical reaction removes immunoglobulins and complement from the surface of DAT (Direct Antiglobulin Test) positive red blood cells. This reagent dissociates IgG and complement from red blood cells, allowing for phenotyping, enhanced adsorption, or denaturing some blood group antigens to aid in completing complex antibody investigations in immunohaematology laboratories.

Components:
This reagent is supplied as a kit containing 0.2 M DTT and 1% papain which has been activated by L-Cysteine.
It is supplied as a kit as 0.2 M DTT 5 mL and 1% Papain 1 mL volumes, to be used directly from the vial.

Special materials and equipment required but not supplied
Calibrated volumetric pipettes.
Centrifuge or cell washer.
Water bath or dry heat incubator.
Phosphate Buffered Saline Solution (PBSS).

Reagent preparation
Thaw before use.
Use reagent as supplied.

Storage and Shelf life after first opening
Store at -20ºC or below.
Discard 24 hours after thawing.
Do not refreeze.
Do not use beyond the notified expiry date.
Prepare ZZAP solution immediately before use.

Warnings and precautions:
This reagent is for healthcare professional use only.
Frozen storage at a temperature significantly above -20ºC may result in an acceleration in the rate of loss of activity 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
Red cells from EDTA samples may be used according to current addition of the British Society for Haematology Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories.

Recommended technique
1. Thaw 5 mL 0.2 M DTT and 1 mL 1% papain.
2. Mix 5 mL 0.2 M DTT and 1 mL 1% Papain with 4 mL of phosphate buffered saline pH 7.0. This is the ZZAP solution, which should be prepared immediately before use.
3. Mix 1 volume of washed packed patient's red cell with 2 volumes of ZZAP solution.
4. Incubate at 37°C for 30 minutes, mixing occasionally.
5. Wash cells 3 times in saline.

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
DAT on cells treated with ZZAP should be significantly reduced compared to untreated cells. Treated cells should be negative for the following antigens: Kell blood group, M, N, S, s, Fy^a and Fy^b.

Performance characteristics
ZZAP is tested to ensure that the solution significantly reduces the DAT when compared to untreated DAT positive cells and to ensure that the K antigen is removed from K positive red cells.

Limitations
Use of these reagents more than 24 hours after thawing may result in erroneous results.
ZZAP treatment of red cells destroys some antigens, notably M, N, S, s, Fy^a and Fy^b and Kell blood groups. Autoantibodies corresponding to these specificities will therefore not be absorbed using the recommended method. Red cell phenotyping for these antigens using red cells treated with the ZZAP reagent using the recommended method will be unreliable.
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.

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.
'Methods in Immunohaematology' by John Judd; Montgomery Scientific Publications; 1988.
The Medical Devices Regulations 2002 (UK Statutory Instruments 2002 No. 618), as amended.

Note – Any serious incident that has occurred in relation to ZZAP 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