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Product Code	Product Name	UDI-DI
PN090	Papain	5055232400598

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

Intended use
For professional use as in vitro diagnostic device accessory used to remove or denature certain antigens from red blood cells to enhance some serological antigen-antibody reactions. This device accessory is intended for use in a variety of red cell immunohematology investigations as an aid to diagnosis in combination with a qualitative antibody identification assay.

Principles of the examination method
Papain is a proteolytic enzyme which enhances reactivity of some red cell antibodies and decreases others in immunohaematological assays. Papain acts by removing antigens on the red cell membrane which changes the electronegativity of the cell and exposes other antigens allowing antibodies to bind without hinderance. Red blood cells are incubated with papain which denatures or removes some red cell antigens from the red cell membrane. The papain treated cells can be used to test serum/plasma to enable identification of red cell antibodies using manual immunohaematological assays.

Components
The reagent is an extract from Papain powder prepared in M/15 phosphate buffer (pH 5.3) and containing Sorbitol (120 mM), Dipotassium EDTA (1 mM) and L-cysteine hydrochloride (25 mM) as an activator.
It is supplied in 5 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 (pH7).
Tube centrifuge or cell washer.
Water bath or dry heat incubator.
Timer.

Reagent preparation
Thaw product before use.
This reagent must not be diluted prior to use.

Storage and shelf life after first opening
Store at -20°C or below.
Once thawed it may be stored at 2-8°C for a maximum of 24 hours after which it should be discarded.
Do not refreeze.
Do not use beyond the expiry date.

Warnings and Precautions
This product is for healthcare professional use only.
Do not use if product is not frozen on receipt.
Frozen storage at a temperature significantly above -20°C may result in an acceleration in the rate of loss of reactivity of the reagent.
Discard within 24 hours after thawing.
The reagent should not be used if turbid or if there is evidence of precipitate, gel or particles present.
Unless antigen stability has been validated, cells treated with this product should not be stored for more than 24 hours at 2 to 8°C.
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 treated with Papain can be used to test 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. Thaw the papain in a 37°C water bath and allow the solution to warm.
2. To 1 volume of concentrated red cells, washed 3 times in Phosphate Buffered Saline Solution (PBSS) pH 7, add 2 volumes of Papain solution.
3. Mix well and incubate in a 37°C water bath for 3 minutes.
4. Remove from water bath and wash cells x 3 in PBSS.
5. Suspend cells to the required % for use in required diluent.
6. Use by standard serological techniques.
7. Read macroscopically. Microscopic reading of the results of enzyme tests is not recommended.

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.
Methods involving enzymes should include procedures to ensure the adequate enzyme treatment of red cells.

Performance Characteristics
The reagent has been standardised using the Azo-albumin technique. The Azo-albumin test value must give a result within 10% of a reference batch of papain which is traceable to NIBSC International Ref. Preparation Papain (92/658). It is confirmed as fit for use using weak anti-Rh sera by standard serological techniques.

Limitations of the examination procedure
M, N, S, Fy^a and Fy^b antigens are destroyed or reduced by the action of enzymes on the cell membrane and this method is therefore not suitable for the detection of all clinically significant antibodies.
This reagent is not standardised for the one stage technique, in which enzyme, serum and red cells are mixed without purposeful delay and incubated together as this technique is not recommended for use in the screening of patient's sera with donor red cells.

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. This includes very slight changes in buffers or in solutions, which may result in sub-optimal pH for enzyme treatment.

Literature references

Directive 98/79/EC on In vitro diagnostic medical devices.
Guidelines for the Blood Transfusion Services in the UK.
British Society for Haematology Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories.
A simple method for the standardisation of proteolytic enzymes used in blood group serology. R Lambert et al Med Lab Sciences 1978 35: 233-238.
The rapid papainisation of red cells for the detection of Rh antibodies. M.M. Izatt et al. Vox Sanguinis 1969 17: 157-160.

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