

Papain Solution Product Insert



IVD

NHS

Blood and Transplant

**For use in serological investigations
For *in vitro* diagnostic use only
Product code PN090
Reagents, NHSBT Liverpool,
14 Estuary Banks, Liverpool L24 8RB
Tel 0151 268 7157**

Intended use

It is intended that this product will be used for serological testing, being useful in resolving mixtures of blood group antibodies. Papain denatures or reduces sialic acid present on red cell membranes

Principles of the examination method

Red blood cells are treated with papain and then used to test serum/plasma to enable identification of any alloantibodies

Components

The product consists of an extract prepared from Papain powder in M/15 phosphate buffer (pH 5.3) and containing Sorbitol (120mM), Dipotassium EDTA (1mM) and L-cysteine hydrochloride (25mM) as an activator. The reagent has been standardised using the Azo-albumin technique to give an optical density of 0.4 to 0.6 on a spectrophotometer at 430nm and/or readings similar to 2 previous lots. It is confirmed as fit for use using weak anti-Rh sera by standard serological technique.

Reagent preparation

Thaw product before use.

Use product as supplied, without addition or dilution.

Storage and shelf life after first opening

Store at -20°C or below

Once thawed it may be stored at 4±2°C for a maximum of 24 hours after which it should be discarded.

Precautions

This product is for professional use only.

Do not re-freeze. Do not use if product is not frozen on receipt

Discard 24 hours after thawing

Do not use if the solution is turbid or there is evidence of gelling

Primary sample collection, handling and storage

Red cells from clotted or EDTA samples may be used, usually less than 7 days old, different time scales apply to recently transfused samples.

Recommended technique:

1. Thaw the papain solution in a 37°C waterbath and allow the solution to warm.
2. To 1 volume of concentrated red cells washed 3 times in Phosphate buffered Saline pH 7, add 2 volumes of Papain solution.

3. Mix well and incubate in a 37°C waterbath for 3 minutes
4. Remove from waterbath and wash cells x 3 in PBS.
5. Suspend cells to 2.3-3% in PBS.
6. Use by standard serological techniques.
7. Read **macroscopically**. Microscopic reading of the results of enzyme tests is not recommended.

Control procedure

Methods involving enzymes should include procedures to ensure the adequate enzyme treatment of red cells. Each batch of tests should be controlled with suitable positive and negative controls e.g. weak anti-D and AB Serum

Interpretation of results

The presence of agglutination indicates a positive result

Limitations of the examination procedure

M, N, S, Fya and Fyb 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. No single test is capable of detecting all clinically significant antibodies. This reagent is not standardised for the one stage technique. One stage mix techniques, in which enzyme, serum and red cells are mixed without purposeful delay and incubated together are not recommended for use in the screening of patients sera with donor red cells. Deviation from the recommended method of use may result in false positive or false negative results. This includes very slight changes in buffers or in solutions, which may result in sub-optimal pH for enzyme treatment. 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

Literature references

This reagent is manufactured in accordance with GMP and 'Guidelines for the Blood Transfusion Services in the U.K. (current edition)
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

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