

Papain Solution Product Insert



IVD



Blood and Transplant

For use in serological investigations
For in vitro use only

Material provided:

Product PN090 5mL for use in red cell immunohaematology tests and in larger volumes for reagent production within NHSBT. 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. Confirmed as fit for use using weak anti-Rh sera by standard serological technique.

Storage and stability:

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

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

Limitations

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.

Specification

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

Each batch has been assessed using NBS Reagents Quality Assurance procedures.

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.

Controls

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

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.

NBS Reagents

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