CE
IVD

Papain for use in serological investigations
For *in vitro* diagnostic use only
Product code PN090

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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
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. The Azo-albumin test value must give a result within 10% of a reference batch of papain. It is confirmed as fit for use using weak anti-Rh sera by standard serological techniques.

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.

Warnings and 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 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 (PBS) 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 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 technique, in which enzyme, serum and red cells are mixed without purposeful delay and incubated together are not recommended for use in the screening of patient's 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

Note – Any serious incident that has occurred in relation to Papain should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established

EC REP
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