ALBAzyme™ Papain Solution

Discard if turbid.
Preservative: <0.1% sodium azide, 0.02% sodium meta-arsenite

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

INTERPRETATION OF LABEL SYMBOLS

LOT Batch code

Use by (YYYY-MM-DD)

Product code

Storage temperature limitation (2°C–8°C)

In vitro diagnostic medical device

Consult instructions for use

Manufacturer

INTENDED USE
ALBAzyme™ Papain Solution is used to treat human red blood cells for use in in vitro immunohematology assays.

SUMMARY AND EXPLANATION
Papain is a protease extracted from papayas (Carica papaya).

Depending on the proteolytic activity of the papain preparation and the degree of exposure, blood group antigens may be removed from the membrane, may exhibit reduced reactivity, may be unaffected or may exhibit enhanced reactivity.

A number of factors contribute to the mechanism by which papain potentiates hemagglutination reactions. Particularly important in this respect are the removal of certain membrane associated structures to create improved access to certain antigens (notably Rh) and a concomitant reduction in the mutually repulsive electronegative charge (sialic acid) on the surface of red blood cells, thereby allowing adjacent red cells to approach each other more closely.

PRINCIPLE OF THE PROCEDURE
Enzyme treatment of red cells can enhance the detection of some blood group antibodies, and can remove certain blood group antigens from the red cell. This action can be used to facilitate the detection of weak antibodies in immunohematology testing and aid in the differentiation of blood group antibodies, especially when multiple antibodies are present.

REAGENT DESCRIPTION
ALBAzyme™ Papain Solution is a papain enzyme solution supplied ready for use. The reagent contains sodium azide (<0.1%), sodium meta-arsenite (0.02%) and bovine albumin.

The product is presented as a 10 mL volume in a vial fitted with a dropper. The volume delivered by the reagent dropper is approximately 40 µL. Bearing this in mind, care should be taken to ensure that appropriate reagent/cell ratios are maintained in all test systems.

PRECAUTIONS
Store at 2 °C – 8 °C.
Do not use if turbid.
Do not dilute.
Do not use beyond the notified expiry date.

It is advisable to minimize product time outside of the refrigerator and to avoid leaving it at room temperature in between use.

Components of this kit contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide buildup.

Handle and dispose of reagents as potentially infectious.

This reagent is for in vitro diagnostic use only.

Once opened the product can be used for 30 days, within the notified expiry date. Regardless of when the product is opened, product usage should not be extended past the original expiry date.

SPECIMEN COLLECTION AND PREPARATION
Specimens should be collected by an acceptable phlebotomy technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2 °C – 8 °C. Blood specimens exhibiting gross hemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiry date of the donation. Reagent red cells, or other cells stored in a preservative solution, may be used until the allocated expiry date.

STABILITY OF REACTION
Enzyme treated cells should be used on the day of preparation.
Test results from ALBAzyme™ Papain Solution treated red cells should be read and interpreted, immediately after centrifugation. Delays may cause dissociation of antigen/antibody complexes resulting in weak positive or false negative reactions.

QUALITY CONTROL
A weak antibody known to give enhanced reactivity with enzyme treated cells may be used for the routine quality control of enzyme treated red cells. Testing of enzyme treated red cells with such an antibody can be used to demonstrate enzyme treatment has been performed correctly and the papain has remained active. Known enzyme treated and native (non-enzyme treated) cells may be included as controls if desired.

When using enzyme treated cells to test plasma or serum samples it is recommended that users include an autologous control (the patient’s own enzyme treated red cells) to aid with the determination of autoantibodies.

PERFORMANCE LIMITATIONS
Only suitably qualified personnel should use the reagent. It is important to refer to the package insert for ALBAzyme™ Papain Solution and to use the recommended treatment procedure stated.
ALBAzyme™ Papain Solution destroys or reduces the expression of many antigens in the MNS, Duffy, Chido/Rodgers, Gerbich, Indian, JMH, and Xg blood group systems.

Prolonged exposure of red cells to ALBAzyme™ Papain Solution will lead to overtreatment of the red blood cells. Red cells that have been over treated may spontaneously aggregate making test interpretation difficult.

For additional information or technical support, contact Product Technical Support at 1-888-228-1990.

BIBLIOGRAPHY


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