

# ALBAzyme™ Papain Solution Kit

REF Z317U

**CAUTION: THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.**

## INTERPRETATION OF LABEL SYMBOLS



Batch code



Use by (YYYY-MM-DD)



Product code



Storage temperature limitation (2 – 8 °C)



*In vitro* diagnostic medical device



Consult instructions for use



Manufacturer



Harmful

## INTENDED USE

ALBAzyme™ Papain Solution Kit is used for the preparation and testing of papainized red blood cells.

The ALBAzyme™ Papain Solution is used to treat human red blood cells with papain for use in *in vitro* immunohematology assays, and the ALBAzyme™ Enzyme Control reagent is for the quality control of papainized red blood cells prior to use.

## 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 blood cells to approach each other more closely.

*Glycine soja* lectin agglutinates red blood cells which have reduced levels of membrane-associated sialic acid. Therefore, the ALBAzyme™ Enzyme Control (*Glycine soja*) reagent produces strong agglutination of enzyme treated red blood cells, and does not agglutinate untreated cells, providing the means to confirm that red blood cells have been successfully papain treated using the ALBAzyme™ Papain Solution.

## PRINCIPLE OF THE TEST

The procedure used is based on the principle of hemagglutination. Red blood cells carrying an antigen, and pretreated with ALBAzyme™ Papain Solution, agglutinate in the presence of the corresponding antibodies.

## 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.

ALBAzyme™ Enzyme Control has been prepared by extracting *Glycine soja* lectin from soyabean seeds and diluting the extract in PBS, bovine serum albumin and 0.1% (w/v) sodium azide.

ALBAzyme™ Papain Solution is presented in 3 mL volumes in vials fitted with droppers  
ALBAzyme™ Enzyme Control Solution is presented in 5 mL volumes in vials fitted with droppers

The volume delivered by each 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 – 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 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.

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 – 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 blood cells, or other cells stored in a preservative solution, may be used until the allocated expiry date.

## MATERIALS

### Materials provided

- ALBAzyme™ Papain Solution
- ALBAzyme™ Enzyme Control (*Glycine soja*)

### Materials required but not provided

- 10 or 12 x 75 mm glass test tubes and tube rack
- Pipettes
- Centrifuge
- Isotonic saline solution (0.9% NaCl)
- Incubator
- Red blood cell sample
- Timer
- Optical aid

## TEST PROCEDURE

### General Information

This reagent has been standardized for use by the technique described below and, therefore, its suitability for use in other techniques cannot be guaranteed. When a test is required to be incubated for a specific period of time, a timer should be used.

## RECOMMENDED TECHNIQUES

### Preparation of papainized cells

1. Wash the red blood cells to be treated three times in isotonic saline solution. Remove as much final supernatant as possible leaving a packed red blood cell pellet. In a tube, add 1 volume of ALBAzyme™ Papain Solution to 1 volume of the washed red blood cell pellet.
2. Incubate at 37 +/- 1 °C for 15 +/- 1 minutes.
3. Wash the treated red blood cells at least once with isotonic saline solution and re-suspend to the required % for use.
4. Perform QC of the papain treated red blood cell suspension by using the ALBAzyme™ Enzyme Control (*Glycine soja*) product, following the instructions below.

### Quality control of papainized cells

1. Add one volume of ALBAzyme™ Enzyme Control reagent to a glass test tube.
2. Add one volume of enzyme treated red blood cells suspended in saline to 3 +/- 1%.
3. Mix the test well.
4. Centrifuge at 900-1000 g (approx. 3400 rpm) for 10 seconds or at a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.
5. Gently shake the tube in order to dislodge the cell button from the bottom and observe macroscopically for agglutination.

## INTERPRETATION OF RESULTS FOR QUALITY

### CONTROL TEST

Agglutination = positive test result  
No agglutination = negative test result

## STABILITY OF REACTION

Enzyme treated cells should be used on the day of preparation.

Test results from ALBAzyme™ Papain Solution treated red blood 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

Quality control of papain treatment should be performed as described above. Inclusion of known enzyme treated and native (non-enzyme treated) cells may be included as controls if desired.

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

The *Glycine soja* component of this kit agglutinates red blood cells that have a reduced level of sialic acid. Cells of a phenotype or condition known to express reduced sialic acid levels will agglutinate regardless of enzyme treatment e.g. Cad, NOR.

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

## BIBLIOGRAPHY

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2. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology, Fourth Edition. Montgomery Scientific Publications, 1998.
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## DATE OF ISSUE

24 September 2014

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