

Papain Solution Kit

ALBAzyme™

For Tube Technique

REF Z317U

- FOR *IN VITRO* DIAGNOSTIC USE
- Discard if turbid
- Preservative: Sodium azide <0.1% (w/v)

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

INTERPRETATION OF LABELING SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)

REF

Product code



Storage temperature limitation (2-8 °C)

IVD

In vitro diagnostic medical device



Consult instructions for use

www.quotientbd.com



Manufacturer



Health Hazard

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*). 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.

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.

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. Papain treated red blood cells may demonstrate enhanced or reduced reactivity in hemagglutination tests.

REAGENT DESCRIPTION

ALBAzyme™ Papain Solution is a papain enzyme solution supplied ready for use. The formulation also contains <0.1% (w/v) sodium azide, 0.02% sodium meta-arsenite and bovine serum albumin.

ALBAzyme™ Enzyme Control has been prepared by extracting *Glycine soja* lectin from soya bean seeds. The formulation also contains bovine serum albumin and 0.1% (w/v) sodium azide.

ALBAzyme™ Papain Solution is presented in 3mL volumes in vials fitted with droppers.

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

NOTE: The volume delivered by each reagent dropper is approximately 40 µL. Care should be taken to ensure that appropriate reagent to cell ratios are maintained in all test systems.

STORAGE

The reagent should be stored at 2-8 °C.

WARNINGS AND PRECAUTIONS

ALBAzyme™ Papain Solution:

EUH208 — Contains Papain. May produce an allergic reaction.

Papain is an irritant therefore before handling, cover exposed wounds with waterproof dressing and cover abraded skin lesions on hands with disposable plastic gloves. Small quantities may be discarded via the drain.

ALBAzyme™ Enzyme Control Solution contains 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 a sink, flush with a large volume of water to prevent azide buildup.

The bovine material which was used has been collected in a USDA approved facility.

This product has components (dropper bulbs) containing dry natural rubber.

This product is for *in vitro* diagnostic use only.

Products should be used by qualified personnel.

Do not use if turbid.

Do not dilute.

Do not use beyond the expiration date.

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

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 a standard collection 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.

Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiration date of the donation.

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

Special care should be taken if hemolyzed samples must be tested. Grossly icteric or contaminated blood specimens should not be used.

MATERIALS

Materials provided

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

Materials required but not provided

- 10 x 75 mm or 12 x 75mm glass test tubes and tube rack
- Pipettes
- Centrifuge
- Isotonic Saline/blood bank saline/PBS
- Heating block/waterbath
- Red blood cell sample
- Timer
- Optical aid (optional)

PROCEDURE

NOTE: 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. When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator's manual provided by the device manufacturer.

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.
2. In a glass test tube, add 1 drop of ALBAzyme™ Papain Solution to 1 drop of the washed red blood cell pellet.
3. Incubate at 37 °C ±1 °C for 14-16 minutes.
4. Wash the treated red blood cells at least once with isotonic saline solution and re-suspend to the required % for use.
5. 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 1 drop of ALBAzyme™ Enzyme Control reagent to a glass test tube.
2. Add 1 drop of enzyme treated red blood cells suspended to 2-4% in saline
3. Mix the contents of the test tube and centrifuge.
4. Suggested centrifuge at 900-1000g (approx. 3400rpm) for 10 seconds or at a time and speed appropriate for the centrifuge used that produces the strongest reaction of positive tests, yet allows easy re-suspension of negative tests.
5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
6. Record results.

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, interpreted and recorded 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.

Agglutination = adequate papain treatment
No agglutination = cells inadequately papain treated

Quality control of reagents is essential and should be performed on the day of use and in accordance with local, state and federal regulations.

LIMITATIONS

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.

The expression of certain red blood cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Heating blocks and waterbaths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.

Gently re-suspend tube tests before reading. Excessive agitation may disrupt weak agglutination and produce false negative results.

Excessive centrifugation can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAzyme™ Papain Solution kit is tested to ensure the product performance specification is achieved.

BIBLIOGRAPHY

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