

ALBAhance™ PEG

(For the potentiation of Indirect Antiglobulin Tests)

REF Z312U

Preservative: 0.1% sodium azide

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

INTERPRETATION OF LABEL SYMBOLS



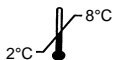
Batch code



Use by (YYYY-MM-DD)



Product code



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



In vitro diagnostic medical device



Consult instructions for use



Harmful



Manufacturer

INTENDED USE

ALBAhance™ PEG is a potentiating reagent for the detection of red cell antibodies in human serum or plasma.

SUMMARY AND EXPLANATION

Polyethylene glycol (PEG) 4000 is a water soluble polymer which can be used as a potentiator in the antiglobulin test. It is suggested that PEG promotes antibody uptake through

steric exclusion of water molecules in the diluent. This factor may help to bring the antigen/antibody in to close proximity resulting in increased antibody binding in such a way that weak antibodies are detected. The reagent has been standardized for use in serological tests according to the procedure described below. The reagent is used in combination with Anti-Human Globulin Anti-IgG reagent in compatibility testing, antibody screening and identification procedures.

PRINCIPLE OF THE TEST

The principle of the test is the agglutination technique which is based on antigen/antibody reaction. ALBAhance™ PEG enhances the sensitivity of this reaction.

REAGENT DESCRIPTION

This reagent is a 20% solution of PEG 4000 in phosphate buffered saline. The formulation also contains 1g/L sodium azide.

The volume delivered by the reagent dropper bottle is approximately 40µl. Bearing this in mind, care should be taken to ensure that appropriate reagent : serum : 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.

This reagent 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 sink, flush with a large volume of water to prevent azide buildup.

Handle and dispose of reagents as potentially infectious.

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

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

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. 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 stored in citrate anticoagulant may be tested until the expiry date of the donation.

MATERIALS

Materials provided

- ALBAhance™ PEG

Materials required but not provided

- Isotonic saline
- Reagent red blood cells
- Anti-Human Globulin Anti-IgG
- IgG sensitized red blood cells
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath @ 37°C
- 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

37°C Indirect Antiglobulin

- Prepare a 2-3% suspension of red blood cells in isotonic saline solution
- Add 1 drop of red blood cell suspension to an appropriately labeled test tube.
- Add 2 drops of the serum or plasma to be tested.
- Add 2 or 4 drops of ALBAhance™ PEG
- Mix the test well and incubate for 15 minutes at 37°C +/- 1°C
- Resuspend the contents of the test tube completely
- Wash the test 4 times with a large excess isotonic saline.
- Centrifuge the test tube.
 - Suggested centrifugation: 1000g for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy resuspension of antigen-negative red blood cells.
- Add 2 drops of Anti-Human Globulin Anti-IgG
- Mix the contents of the test tube well and centrifuge.
 - Suggested centrifugation: 1000g for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy resuspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.
- Record results.

STABILITY OF REACTION

Test results should be read and interpreted immediately after centrifugation. Delays may cause dissociation of antigen/antibody complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL

Quality control of reagents should be performed on each day of use with known positive and negative red blood cells, and in accordance with local, state and federal regulations.

The use of IgG sensitized red blood cells is essential to confirm the activity of Anti-Human Globulin Anti-IgG reagents. Add 1 drop of IgG sensitised red blood cells to all negative tests and repeat the centrifugation and reading process. A positive result indicates the presence of active Anti-Human globulin Anti-IgG. Tests in which negative results are obtained with this procedure should be considered invalid and repeated if necessary.

PERFORMANCE LIMITATIONS

Any saline present after the completion of the wash phase may dilute the Anti-Human Globulin Anti-IgG reagent beyond its optimal working concentration. It is therefore important to ensure that the maximum amount of wash fluid is removed after each centrifugation stage.

The precipitate formed after PEG addition makes the washing procedure very critical. Therefore, to ensure efficient washing the tubes must be washed 4 times in an excess of isotonic saline.

If automated cell washers are used, the performance and cleanliness of the instrument should be checked frequently.

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

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

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

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.

Suppressed or weak expression of blood group antigens may give rise to false-negative reactions.

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 ALBAhance™ PEG is tested by FDA recommended methods to ensure suitable reactivity. The performance of the product is dependant on adhering to the methods recommended in the instructions for use.

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

BIBLIOGRAPHY

1. Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008.
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