ALBAhance™ PEG

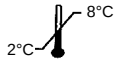
For the potentiation of Indirect Antiglobulin Tests

REF Z312U

Preservative: 0.1% sodium azide

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

INTERPRETATION OF LABELING SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
	Storage temperature limitation (2°C– 8°C)
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
	Manufacturer
REF	Product Code

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 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 0.1% (w/v) sodium azide.
The volume delivered by the reagent dropper bottle is approximately 40 µL; bearing this in mind, care should be taken to ensure that appropriate reagent: serum: cell ratios are maintained in all test systems.

STORAGE CONDITIONS

The reagent should be stored at 2-8 °C. Do not use if turbid. Do not dilute. Do not use beyond the notified expiry date.

PRECAUTIONS FOR USE AND DISPOSAL

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 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 refrigerated temperatures. Blood specimens exhibiting contamination should not be used. Extreme care should be taken if hemolyzed samples must be tested. 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.

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 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath
- Optical aid (opt)
- Timer

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

1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent Red Blood Cells may be used directly from the vial or according to the manufacturer's instructions).
2. Add 2 drops of the serum or plasma to be tested to a glass test tube.
3. Add 1 drop of red blood cell suspension. Steps 2 and 3 may be performed in either order.

NOTE: If desired, a direct test may be performed prior to the addition of ALBAhance™ PEG.

4. Add 2 or 4 drops of ALBAhance™ PEG.
5. Mix the contents of the test tube well and incubate at 37 °C ± 1 °C for 15-20 minutes.
6. Resuspend the contents of the test tube completely.
7. Wash the test 3-4 times with a large excess of isotonic saline (*e.g.* 4 mL of saline per 10 (or 12) x 75 mm glass test tube).

NOTE: (i) allow adequate spin time to sediment the red blood cells.
(ii) make sure that the residual saline is removed at the end of each wash.

8. Add 2 drops of Anti-Human Globulin Anti-IgG to each test tube, or as directed by the AHG manufacturer's instructions.
9. Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10 seconds or 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.
10. After centrifugation, gently shake the test tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
11. Record results.
12. To all negative tests add IgG sensitized red blood cells and follow manufacturer's instructions. Any test which does not show a positive reaction should be considered invalid and repeated.

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 is essential and should be performed on each day of use, and in accordance with local, state and federal regulations.

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.

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 re-suspend 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. 17th ed. Bethesda, MD: AABB, 2011
2. Issitt PD, Anstee DJ. Applied Blood Group Serology, Fourth Edition. Montgomery Scientific Publications, Durham, NC USA 1998.
3. Daniels G.; Human Blood Groups. Blackwell Science Ltd. 1995.
4. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993

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