LISS ADDITIVE REAGENT

ALBAhance™

REF **Z333U**

- **No US Standard of Potency**
- **Discard if turbid**
- **Preservative: 0.09% 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)
2°C 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult Instructions for Use
REF	Product code
	Manufacturer

INTENDED USE

ALBAhance™ LISS Additive Reagent is intended for use as a potentiator in antibody detection, antibody identification and compatibility test procedures.

SUMMARY AND EXPLANATION

A substantial reduction in the incubation time for antigen/antibody mixtures can be achieved when the red blood cells and serum are suspended in a LISS medium. It is also recognized that most antibodies will show an increase in the test sensitivity when LISS is incorporated into the test medium.

PRINCIPLE OF THE PROCEDURE

ALBAhance™ LISS Additive Reagent is added directly to antibody detection, antibody identification or cross-match reagents to reduce the ionic strength of the testing environment. There is enhancement of antigen-antibody interactions during incubation. Because antibody uptake is enhanced, incubation periods of low ionic test systems are generally shorter than those of routine saline/albumin tests.

REAGENT DESCRIPTION

ALBAhance™ LISS Additive Reagent is a low ionic reagent containing sodium azide 0.09% (w/v) as a preservative. ALBAhance™ LISS Additive Reagent is to be used as supplied following the directions detailed in this insert.

The volume delivered by the reagent dropper bottle is approximately 40 µL; bearing this in mind, care should be taken to ensure that appropriate 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 0.09% (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 build-up.
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.
Do not use collection tubes that contain serum or plasma/cell separation media.

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.

Materials provided

- ALBAhance™ LISS Additive Reagent

Additional Materials and Reagents Required

- Patient/donor serum/plasma
- Isotonic saline
- Reagent red blood cells for antibody detection or identification
- Antiglobulin Reagent
- IgG sensitized red blood cells
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath
- Timer
- Optical aid (opt)

RECOMMENDED TECHNIQUE

37 °C Indirect Antiglobulin Test

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™ LISS Additive Reagent or prior to incubation.

4. Add 2 drops of ALBAhance™ LISS Additive Reagent.
5. Mix the contents of the test tube well and incubate at 37 °C ± 1 °C for 15-20 minutes.

Optional Steps (6-8)

6. Following incubation at 37 °C, the test may be examined macroscopically for evidence of agglutination.
   Mix the contents of the test tube 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.
7. Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.
8. Record results.

9. 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.

10. Add 2 drops of Anti-Human Globulin to each test tube, or as directed by the AHG manufacturer's instructions.
11. 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.
12. 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.

13. Record results.
14. 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.

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.

INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

PERFORMANCE LIMITATIONS

Direct antiglobulin test positive samples will react by the indirect antiglobulin test irrespective of their antigen status.

Dri-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 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.

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™ LISS Additive Reagent is tested by the method detailed in the package insert against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

BIBLIOGRAPHY

Technical Manual. 17th ed. Bethesda, MD: AABB, 2011

Low B, Messeter L. Antiglobulin test in low ionic strength salt solution for rapid antibody screening and crossmatching. Vox Sang 1974; 26:53.

Moore HC, Mollison PL. Use of a low ionic strength medium in manual tests for antibody detection. Transfusion 1976; 16:291.

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