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 LABEL SYMBOLS

<table>
<thead>
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<th>SYMBOL</th>
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<tr>
<td>LOT</td>
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<td>Use by (YYYY-MM-DD)</td>
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<td>Storage temperature limitation (2-8 °C)</td>
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<td>In vitro diagnostic medical device</td>
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<td>Consult instructions for use</td>
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<td>Product code</td>
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<td>Manufacturer</td>
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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 0.06% (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.

TEST PROCEDURE

37 °C Indirect Anti-globulin Test
- Add 2 drops of patient’s serum/plasma to a test tube.
- Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Note that reagent red cells may be used as provided by the manufacturer, i.e. as preservative-suspended red cells.
- Add 2 drops of ALBAhance™ LISS Additive Reagent Mix the test well and incubate for 15-20 minutes at 37 °C ± 1 °C
- [Opt] 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 10-20 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 re-suspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.
- Wash the test at least 3 times with a large excess isotonic saline, e.g. 4 mL of saline per 12 (or 10) x 75 mm glass test tubes.

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

- Add Antiglobulin Reagent to each test tube in the amount specified in the manufacturer's product insert.
- Mix the contents of the test tube well and centrifuge.
- Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10-20 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. Negative reactions may be examined with an optical aid.
- Record results.
- Add IgG sensitized red blood cells to confirm the validity of negative test 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.

**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**


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