

INSTRUCTIONS FOR USE

BAG-LO-ION



LISS modified

FOR IN VITRO DIAGNOSTIC USE

1. Description of product

BAG-LO-ION is a modified LISS (Low Ionic Strength Solution) reagent containing among other ingredients low salt bovine albumin. BAG-LO-ION can be used in tests for antibody detection, antibody identification and compatibility testing (crossmatch) to enhance antigen-antibody reactions and to shorten incubation periods.

2. Principle of the test

BAG-LO-ION is added directly to tests for antibody detection, antibody identification and compatibility testing. The low ionic strength of BAG-LO-ION reduces the ion concentration in the testing environment and the red cells swell in the hypotonic solution.

In addition high-molecular ingredients such as bovine albumin decrease the mutual repulsion of the red cells. This results in enhancement of antigen-antibody reactions and promotes the detection of some alloantibodies of IgG type. Because antibody uptake of red cells is enhanced, in comparison to NaCl tests the incubation period can be shortened.

3. Storage and stability

Store BAG-LO-ION at 2...8°C. Do not freeze! Allow the reagent to come to room temperature (18...25°C) before use and store again at 2...8°C immediately after use.

Once it has been opened the first time, the reagent may be used up to the expiration date indicated on the label if the specified storage conditions are observed. Do not use BAG-LO-ION past the expiration date indicated on the label.

4. Preparation of samples

Blood samples should be collected by approved medical procedure. Blood collected with (EDTA, citrate) or without anticoagulant is acceptable. Do not use hemolytic samples! Testing should take place without delay whenever possible. If a delay in testing is unavoidable, red cells samples, sera and plasmas should be stored at 2...8°C. Serum and plasma not tested within two days can be stored at -20...-80°C.

Prolonged storage of red cells prior to testing may result in deterioration of red cell antigens and can lead to false reactions (see 9. Important Notes/Limitations of the Method).

5. Additional materials required

Reagent red blood cells with known phenotype for antibody detection and identification

Anti-Human Globulin (with anti-IgG)

Control cells sensitized with IgG

Isotonic NaCl solution

Test tubes (75 x 12 mm)

Single-use Pasteur pipettes

37°C waterbath

Centrifuge

6. Test procedure

1. Place 2 drops of the serum/plasma to be tested into a labeled test tube.
2. Add 1 drop of 2 – 5% suspension of red cells (reagent red cells or proband red cells washed at least once in isotonic NaCl solution).
3. Add 2 drops of BAG-LO-ION and mix well.
4. Incubate for 10 minutes at 37°C.
5. Centrifuge for 1 minute at 400 x g (1500 rpm) or at an alternative rpm with an appropriate time adjustment.

6. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.
7. Wash the cells 3 x with isotonic saline.
8. Decant the supernatant completely to ensure the removal of residual saline and a resultant "dry" red cell button.
9. Add 2 drops of Anti-Human Globulin (with anti-IgG) (refer to the manufacturer Instructions for Use for Anti-Human Globulin) and mix gently but thoroughly.
10. Centrifuge for 1 minute at 400 x g (1500 rpm) or at an alternative rpm with an appropriate time adjustment.
11. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.
12. Confirm the validity of negative or only weak results with IgG sensitized cells in accordance with the manufacturer Instructions for Use.

Comments: For detection of certain cold-reactive antibodies it is recommended to centrifuge and to examine for agglutination prior incubation at 37°C.
Always a control for autoagglutination (patient red cells + patient serum) should be carried along.
For checking the specificity it is recommended to perform a test with a known antibody, showing an enhanced antigen-antibody reaction with BAG-LO-ION, and antigen-positive and antigen-negative red blood cells in periodic intervals.

7. Interpretation of the results

An agglutination or hemolysis of the red cells indicates the presence of one or several antibodies in the serum/plasma tested.

No agglutination or hemolysis of the red cells indicates the absence of antibodies against antigens of the used red cells in the serum/plasma tested (within the accepted limitations of the test procedure).

The limitations of the method must be considered when interpreting the results (see 9. Important Notes/Limitations of the Method).

8. Stability of reactions

All test results must be interpreted immediately once centrifugation is completed.

9. Important notes/limitations of the method

1. BAG-LO-ION is suitable for in vitro diagnostic use only and may only be used by trained, qualified personnel.
2. Observe the order to drop first serum and red cells and to add BAG-LO-ION after this (see Test procedure), otherwise hemolysis of the red cells could happen.
3. Not all antibodies are reactive in a test system with low ionic strength respectively show an enhanced antigen-antibody interaction such as some IgM antibodies.
4. Complement-binding cold-reactive antibodies often demonstrate no agglutination after the anti-globulin phase.
5. In case of using plasma it should be noted that anticoagulants can effect the detection of antibodies (e.g. EDTA plasma in case of complement-binding antibodies, dilution effect in case of citrate plasma)..
6. Red cells reacting positive in a direct antiglobulin test are unsuitable for the indirect antiglobulin test.
7. Microbial or chemical contamination of BAG-LO-ION must be absolutely avoided because this shortens the shelf life of the product and can lead to false results. Do not use BAG-LO-ION when signs of contamination are observed.
8. False negative results or unexpected weak reactions may be caused by an insufficient cell concentration, insufficient incubation temperature or time and/or insufficient centrifugation, but also by storing the red cells/sera/plasmas for too long and/or under inappropriate conditions. Reading the results of the test too late, agitating the red cell sediment too strongly, and other deviations from the indicated test procedure can also lead to weaker or false negative results.
9. In general, false negative or false positive results can result from inappropriate techniques, incorrect centrifugation or incubation and/or contaminated materials and samples.
10. Whether transfusions or transplantation have taken place should always be taken into consideration when interpreting the results. Any history of transfusions and/or transplantation, as well as the patient's medication history, should be taken into consideration when interpreting results.

10. Performance characteristics

The effectiveness of BAG-LO-ION has been examined under the test conditions indicated in this Instruction for Use with clinical serum and plasma samples and commercial available human antisera. The study demonstrated BAG-LO-ION enhance and accelerate the antigen-antibody interactions in case of many antibodies, particularly antibodies of IgG type. Unspecific reactions were not found.

11. Warnings and instructions for disposal

All materials of biological origin used for the test, especially the human specimen to be tested, should be regarded as potentially infectious. For bovine albumin, used for the production of BAG-LO-ION, exist a health certificate for use in in-vitro diagnostic device.

When handling biological material appropriate safety precautions are recommended (Do not pipette by mouth; wear disposable gloves while handling biological material and performing the test; disinfect hands when finished the test). Biological material should be inactivated before disposal (e.g. in an autoclave). Disposables should be autoclaved or incinerated after use. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a suitable standard disinfectant or 70% alcohol. Material used to clean spills, including gloves, should be inactivated before disposal (e.g. in an autoclave).

BAG-LO-ION contains NaN_3 as a preservative. The reagent contains < 0.1% NaN_3 which is not considered to be a harmful concentration. Nevertheless avoid contact with the skin and mucous membranes. The copper and lead used in some plumbing systems can react with azides to form explosive salts. The quantities of azide used in this reagents are small; nevertheless when disposing of azide-containing materials, they should be flushed away with a large volume of water.

Disposal of all specimen and test materials should be in accordance with state and local law.

12. Package Sizes








See price list.

13. Bibliography

Metaxas-Bühler M., Blutgruppen und Transfusion, Verlag Hans Huber 1994

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

Moore H.C., Mollison P.L., Use of low ionic strength medium in manual tests for antibody detection. Transfusion 1976, 16:291

Explanation of symbols used on Labelling	
	For in vitro diagnostic use
	Storage temperature
	Batch code
	Use by
	Catalogue number
	Consult instructions for use
	Contains Natriumazide

Instructions for use	Issue: July 2007
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