Bovine Serum Albumin 22% IVD

PRODUCT CODE
SB006

INTENDED USE
Serological albumin was first recognized as a potentiator of certain antigen-antibody interactions in 1945 by Diamond. Bovine Albumin is mainly used to enhance the reactivity of blood grouping and typing antibodies in direct agglutination tests. Bovine Albumin also enhances the reactivity and sensitivity of indirect antiglobulin test which is used for compatibility testing, antibody screening, identification and titration.

PRINCIPLE
Agglutination of antibody coated red cells depends upon the class and type of antibody involved and the characteristics of the reaction medium such as ionic strength and pH. Incomplete antibodies of IgG class, especially those with Rh specifity, agglutinate red cells if the zeta potential between the red cells is adjusted by addition of colloids and salts such as Bovine albumin reagent. Addition of BSA enhances such immunological reactions and increases test sensitivity.

COMPOSITION AND REAGENT PREPARATION
22% Serological Albumin is prepared from a mixture of bovine serum albumin, and buffered saline. The polymer content of the Polymer Enhanced BSA is increased naturally by a process modification. No artificial avidity enhancers or high molecular weight agglutination potentiators are added to any BSA preparation. None of the BSA reagents contain sodium caprylate. Each BSA reagent is supplied at optimal dilution for use with all the recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see Vial Labels.

WARNINGS AND PRECAUTIONS
Sodium azide at a final concentration of < 0.1% w/w is added as a preservative. It can cause high explosive metal azide combinations with lead and cooper. When pouring rinse with a lot of water. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded. Caution: All blood products should be treated as potentially infectious. No known regime of testing can completely guarantee that any product derived from blood is incapable of transmitting infectious agents. Care should be exercised in the use and the disposal of the container and its contents.

STORAGE AND STABILITY
Do not freeze. Reagent vials should be stored at 2-8ºC. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

ADDITIONAL REAGENTS AND MATERIALS REQUIRED
Test tubes, Serological pipettes, Pasteur pipettes, Human red blood cells with specific antigen reacting with the antibody to be titrated, Centrifuge, Incubator, Isotonic saline, Anti-Human Globulin reagent (AHG), Coombs control cells, AB Neutral human serum.

SAMPLE COLLECTION AND PREPARATION
No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8°C if not tested immediately. Do not use haemolysed samples. Donor unites can be tested up to the end of their dating. For indirect antiglobulin test, serum from fresh clotted whole blood should be used.

RECOMMENDED TECHNIQUES

ANTIBODY TITRATION TEST
1. a) Prepare a 2-5% suspension of test erythrocytes with specific antigen reacting with antibody to be titrated in Bovine Albumin reagent.
   b) Also prepare a 2-5% suspension of patient's red cells in Bovine Albumin reagent
2. Label ten test tubes (1-10) and make progressive dilutions of the patient serum as indicated below
   a) Pipette 0.1 ml of AB Neutral serum into each test tube except the first tube.
   b) Pipette 0.1 ml of the patient serum into first two tubes only.
   c) After mixing the contents of the second tube thoroughly, transfer 0.1 ml of the mixture to the third tube.
   Continue the serial dilution by transfer up to tube No. 10; discard 0.1 ml of the mixture from the last tube.
3. To tube No. 1 to 9 add one drop of Albumin suspended selected red blood cells, (as prepared in point No. a) above and mix well
4. To tube No. 10, add one drop of patient red cells suspended in albumin (as prepared in point No.1b above) and mix well.
5. Incubate all the tubes at 37°C for a minimum of 15 minutes
6. Centrifuge all the tubes for one minute at 700 g (2000 rpm) or with alternative rpm and adapted time.
7. Very gently, resuspend the cell buttons and observe for agglutination macroscopically.
8. Antiglobulin test should be performed on all tubes which do not show a very strong agglutination.

BROAD SPECTRUM COMPATIBILITY TEST
MAJOR CROSS MATCH PROCEDURE
INITIAL PHASE
1. Label two test tubes as A (for albumin) and B (for saline); depending upon the number of donors to be cross matched, as many pairs of such labelled tubes would be required.
2. Prepare a 2-5% suspension of the red cells to be tested in isotonic saline.
3. Pipette two drops of recipient serum in both the labelled test tubes.
4. Pipette one drop of donor red cells in both the labelled test tubes and mix well.
5. Only to the albumin tube (A) add two drops of Bovine Albumin reagent and mix well.
6. Centrifuge both the tubes for one minute at 1500 rpm or with alternative rpm and adapted time.
7. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.
8. Proceed to incubation phase.

INCUBATION PHASE
1. Incubate the saline tube at room temperature and the albumin tube at 37°C for fifteen minutes.
2. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.
3. Proceed to the antiglobulin phase.

ANTIGLOBULIN PHASE
1. Only the albumin tubes (A) are tested in the antiglobulin phase.
2. Wash the mixture of red blood cells and serum thoroughly with isotonic saline for a minimum of three times. Decant completely after last wash.
3. Place two drops of Anti Human Globulin reagent into the test tube containing the sedimented cells and mix well.
4. Centrifuge for one minute at 1500 rpm or with alternative rpm and adapted time.
5. Very gently, resuspend the cells and observe for agglutination macroscopically.

INTERPRETATIONOF RESULTS
COMPATIBILITY TEST
In all phases of the compatibility test, if no agglutination or haemolysis is observed, then the patient and the donor may be considered compatible. If haemolysis or agglutination at any point till the completion of the antiglobulin phase is observed, the patient and donor are considered incompatible.

ANTIBODY TITRATION TEST
The end point of the titration is the reciprocal of the dilution in the last tube showing agglutination.

CAUTION
The product is derived from bovine blood collected at a USDA licensed establishment. The cattle received ante- and post mortem health inspection and they were free from infectious and contagious diseases. All donor animals were soured in the United States, a country in which Bovine Spongiform Encephalopathy (BSE) is not known to exist. Blood collection records are incorporated into the manufacturing batch documents.

REMARKS
1. If plasma is used in the indirect antiglobulin test, the complement dependend antibodies may not be detected due to the absence of calcium.
2. To all negative test results, after the antiglobulin test phase, one drop of Coombs Control cells should be added. If the Coombs Control cells do not agglutinin, then the compatibility test must be repeated.
3. Red blood cells showing a positive direct antiglobulin test should not be used for the indirect antiglobulin test.
4. Bovine albumin will not bring about agglutination of red cells by all IgG blood grouping typing antibodies.

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5. As under centrifugation or over centrifugation can lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required for achieving the desired results.
6. After use the reagent should be immediately recapped and replaced to 2-8°C storage. The product is guaranteed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

DISCLAIMER

1. The user is responsible for the performance of the reagents by any methods other than those mentioned in the Recommended Techniques.
2. Any deviations from the Recommended Techniques should be validated prior to use.

BIBLIOGRAPHY

1. Widman FK. Technical Manual, 9th Edition. American Association of Blood Banks, Arlington, VA, 1985; Chapter 8
2. Race RR, Sanger R. Blood Groups in Man, 6th Edition. Blackwell Scientific, Oxford 1975; Chapter 2
3. Mollison PL. Blood Transfusion in Clinical Medicine, 8th Edition. Blackwell Scientific, Oxford 1987; Chapter 7
4. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6
5. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Fourth Edition 2000, Section 3.
6. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, 5, 145- 150.

SYMBOL ON LABELS