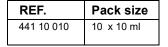


Bovine Serum Albumin (BSA)



Intended Use

Bovine Serum Albumin is intended for the in-vitro use.

Introduction

Specific antigens in the first stage of agglutination but will not produce visible agglutination without the use of special techniques. Addition of bovine albumin to the cell suspension enables some of these antibodies to complete the second stage of agglutination. Albumin has been shown to enhance the sensitivity of the indirect antiglobulin test for some antibody specificites.

Reagents

SDI 22% and 30% Bovine Albumin reagents are prepared from Bovine Serum Albumin. The polymer content of SDI 22% polymer Enhanced Bovine Albumin is increased naturally by a process modification. No artificial avidity enhancers or high molecular weight agglutination potentiators are added to BSA. These reagents do not contain sodium caprylate. Sodium azide at 0.1 % is added as a preservative. These reagents should be used as supplied by the methods described ; their suitability for use in other techniques must be determined by the user.

Precautions and warnings

For in-vitro diagnostic use only. Store at 2-8 °C when not in use . Do not freeze or expose to elevated temperatures. Market turbidity may indicate reagent deterioration or contamination. SDI Bovine Albumin solutions are derived from accredited and inspected herds from areas where the risk of bovine spongiform encephalopathy is negligible. Additionally, during the manufacturing process the reagents are subjected to conditions of high temperature and low PH for extended periods. Such procedures have been shown to completely inactive BSE-like agent.

Specimen collection and preservation

Fresh serum obtained from a fully clotted specimen should be used in compatibility or antibody identification procedures. Red cells obtained from samples with or without anticoagulants can be used in antigen detection tests.Draw a blood specimen using an acceptable phlebotomy technique. Testing should be performed as soon as possible. If testing is delayed store samples at 2 - 8 °C. Serum or

Plasma can be separated from the cells and frozen.

Technique - Albumin Replacement Method

1- Prepare a 2 - 3% suspension of red cells in isotonic buffered saline (pH 6.9)

- 2- Place in a glass test tube
 - Volume of serum or plasma
- 1 Volume of 2-3% cell suspension 3 Mix well and incubate at 37 °C for 45 90 minutes.
- 4 With a fine pipette remove the supernatant saline-serum mixture, leaving the button of red cells. 5- Add one volume of SDI 22% Bovine Albumin.Take care not
- to disturb the cell button.
- 6- Without mixing reincubate at 37 °C for 15-30 minutes.
- 7- Examine for agglutination. Reactions may be examined with an optical aid, or microscopically. Record results.

Technique - Albumin Displacement Method

- 1- Follow steps 1-3 of albumin replacement method.
- Upwardly displace the supernatant saline-serum mixtureby carefully allowing one volume of SDI 30% Bovine albumin to run down the inside wall of the test tube. 3- Follow steps 6 and 7 of the Albumin Replacement Method.

Technique - Albumin Mix Method

- 1- Prepare a 2 3% suspension of red cells in isotonic buffered saline (pH 6.9)
- 2- Place in a glass test tube

 - 1 Volume of serum or plasma 1 Volume of 2-3% cell suspension
 - 2 Volumes of SDI 22% Bovin Albumin
- A bit well and incubate at 37 °C for 15 60 minutes.
 Centrifuge at 900 1000 RCF for 30 seconds.
- Gently resuspend the cell button and Examine for agglutination. 5 Record result.

Technique - Indirect Antiglobulin Test

- 1- Follow steps 1-3 of albumin mix method
- Wash the cells 3-4 times in isotonics buffered saline, decanting 2 the saline completely after each wash
- Add two volumes of SDI Anti Human Globulin to the dry cell 3button
- Mix gently and centrifuge at 900- 100 RCF for 15 seconds
 Gently resuspend the cell button and Examine for agglutination. Record result
- Confirm validity of all negative reactions by using IgG sensitised 6 red cells, such as Coombs Control cells

Technique - Antibody Titration Procedure

- 1- Prepare doubling dilution of test serum in either normal group AB serum or 6% bovine albumin (the latte can be prepared by mixing 1 part SDI 30% bovine albumin with 4 parts isotonic buffered saline
- 2- Prepare a 2% suspension of appropriate washed red cells in SDI 22% or 30% bovine albumin
- 3- Add 1 volume of 2% cell suspension to 1 volume of each serum dilution mix well and incubate at 37 °C for 15 60 minutes 4- Centrifuge at 900 1000 rcf for 30 seconds
- Gently resuspend the cell button and Examine for agglutination. 5-Record result
- 6- An antiglobulin test may be preformed on those cells showing weak or negative results
- Alternatively a time appropriate for the centrifuge being used may be determined i.e., that which produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.

Stability of the reaction

Following the recommended procedures, all tests should be read immediately and results interpreted without delay. Delays in reading or delays in completion of washing steps where appropriate may result in dissociation of antigen antibody complexes, leading to false negative or weak positive reactions.



Limitations

Bovine albumin will not enhance the reactivity of all blood group antibodies.

Bovine albumin solutions should not be used as negative controls for potentiated IgG blood grouping reagents. False positive or false negative results may occur due to improper technique or contaminated test materials.

Specific Performance Characteristics

SDI 22% and 30% Bovine Albumin solution have been shown to enhance agglutination of Rh and other antibodies when used according to insert methodologies. Each lot is tested to assure specificity in an antibody free system with red cells known to process the most frequently inherited blood group antigens.

SYMBOLS IN PRODUCT LABELLING

- IVD For in-vitro diagnostic use LOT REF
 - Batch Code/Lot number
- Catalogue Number i Consult instructions for use
- ۰ł°
 - **Temperature Limitation**
- Σ Use by/Expiration Date
- /!\ CAUTION. Consult instructions for use
 - Manufactured by



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