

**GENESIS**

## Instructions For Use

# Bovine serum albumin 22%

Product	Cat no.	size
Bovine serum albumin 22%	4107 101	1*10 ml

### INTENDED USE

Bovine serum Albumin is mainly used to enhance the reactivity of blood grouping and typing antibodies in direct agglutination tests. Bovine serum Albumin also enhances the reactivity and sensitivity of indirect anti-globulin test which is used for compatibility testing, antibody screening, identification and titration.

### BACKGROUND

Serological albumin was first recognized as a potentiator of certain antigen-antibody interactions in 1945 by Diamond. Since then, methods employing Bovine Serum albumin have been widely used for the detection or quantitation of antibodies. Bovine Serum albumin has also been shown to enhance the sensitivity of the indirect anti-globulin test for some antibody specificities.

### PRINCIPLE OF THE METHOD

Hemagglutination technique.

Incomplete antibodies (IgG) do not agglutinate red blood cells in saline medium but will cause firm agglutination when mixed or suspended in 22% BSA. No other protein has been found to be as effective as BSA while giving negative reactions free from pseudo agglutination.

### COMPOSITION

Bovine serum albumin reagent	bovine serum albumin buffered saline Sodium azide <0.1%
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### STORAGE.

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels

### ADDITIONAL EQUIPMENT

- Test tubes (8X50mm),
- Pipettes,
- Centrifuge
- 0.9% NaCl saline.
- General laboratory equipment

### SPECIMEN

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 anti-globulin test, serum from fresh clotted whole blood should be used.

### PROCEDURE

#### 1).detection of incomplete antibodies (IgG):

##### A) Albumin replacement technique:

- 1- Prepare a 2 - 3% suspension of red cells in isotonic buffered saline
- 2- Place in a labelled test tube: 1 volume test serum  
1 volume test 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 spectrum 22% Bovine Albumin.Taking 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.

##### B) Albumin displacement technique:

- 1- Follow step 1,2,3 of Albumin replacement technique (A).
2. Add 1 volume of Bovine Albumin (22% w/v) to the above tube from the side wall of the test tube to displace the saline mixture.
3. Incubate further at 37 C for 30 minutes.
4. Observe the results macroscopically and microscopically.

Symbols in Product Labeling	
EC	Authorized Representative
REP	Expiry date
IVD	For in-vitro diagnostic use
REF	CAUTION, consult instructions for use
LOT	Lot number
	Manufactured by
	Consult instructions for use
	Temperature Limit

#### 2)Albumin mixed Technique(Room Temperature Saline Phase)

- 1.Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
- 2.Place in a labelled test tube: 1 volumes test serum  
1 volume test cell suspension  
2 volumes 22%.bovine albumin
- 3.Mix thoroughly and incubate at 18-25°C for 5-30 minutes.
- 4.Centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
- 5.Examine supernatant for haemolysis, then gently resuspend cell button and examine macroscopically for agglutination.

#### 3).Albumin Mix Technique (37°C)

- 1.Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
- 2.Place in a labelled test tube: 1 volumes test serum  
1 volume test cell suspension  
2 volumes 22%.bovine albumin
3. Mix well and incubate at 37 oC for 15 - 60 minutes..
- 4.Centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
- 5.Examine supernatant for haemolysis, then gently resuspend cell button and examine macroscopically for agglutination.

#### 4). Indirect Anti-globulin Technique

1. Prepare a 2-4% suspension of washed test red cells in PBS.
2. Place in a labeled test tube: 2 volumes of test serum + 1 volume of test 3% red cell suspension + 1 volume of test 22% of genesis Bovine albumin.
3. Mix thoroughly and incubate at 37°C for 15 minutes.
4. Wash test red cells 4 times with PBS, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.
5. Add 2 volumes of Anti-Human Globulin to each dry cell button.
6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
7. Gently resuspend red cell button and read macroscopically for agglutination

#### 5). Antibody Titration Technique

- 1.Prepare a 2-3% suspension of red cells in Rapid Labs 22% Serological Albumin.
- 2.Prepare doubling dilutions of test serum in inert AB serum.
- 3.Add 1 volume of red cell suspension to 1 volume of each dilution.
- 4.Mix thoroughly and incubate at 37°C for 15-60 minutes.
- 5.Centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
- 6.Gently resuspend each cell button and read macroscopically for Agglutination

### Interpretation of test results

1. Positive: Agglutination of test red cells constitutes positive test result within accepted limitations of the test procedure.
2. Negative: No agglutination of the test red cells constitutes negative test result within accepted limitations.

### Stability of the reactions

1. Washing steps should be completed without interruption and tests centrifuged and read immediately after addition of the reagent.
2. Delays may result in dissociation of antigen-antibody complexes, causing false negative or weak positive results. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

### PERFORMANCE CHARACTERISTICS

Genesis Bovine Albumin 22% w/v is rigorously tested and found to be free from any non-specific as well as auto-agglutination reactions.

## PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only
- Products should be used by qualified personnel
- Do not use beyond the expiration date
- Do not use if turbid
- The reagents contain 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.

## BIBLIOGRAPHY

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- Pirofsky B. American Association of Blood Banks:59 (1972)
- The anti-complement reactivity low ionic methods as published by the FDA. Recommended methods for Anti-Human Globulin Evaluation, Oct., 1994 rev.

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