N.S. BIO-TEC

Bovine albumin

22% and 30% Solutions Serological Reagent

REF.:ANTI-BA-1010

Principle

Although incomplete antibodies have the ability to combine with their specific antigens in the first stage of agglutination, they do not produce visible agglutination without the use of special techniques. The addition of serological albumin to the cell suspension enables some of these antibodies to complete the second stage of agglutination. The use of serological albumin has been shown to have the ability of enhancing the sensitivity of the indirect antiglobulin test for some antibody specificities.

Summary

NS Biotec Serological Albumin reagent has been prepared from bovine serum albumin. No artificial avidity enhancers or high molecular weight agglutination potentiators have been added. The reagent does not contain sodium caprylate and Sodium Azide (0.1%) has been added as a preservative.

SAMPLES

Fresh serum obtained from a fully clotted specimen should be used for compatibility or antibody identification procedures. Red cells from samples with or without anticoagulant may be used in antigen detection tests. Ideally samples should be tested as soon as possible. However samples may be stored between 2°C and 8°C. Serum and plasma may be separated from cells and frozen.

TEST PROCEDURES

TECHNIQUE – ALBUMIN REPLACEMENT METHOD

1. Prepare a 2-3% suspension of red cells in isotonic buffered saline (pH6.9).
2. Into a glass tube dispense 100µl of serum or plasma and the 2-3%cell suspension.
3. Mix well and incubate at 37°C for 45 – 90 minutes.
4. Remove the supernatant saline-serum mixture leaving the button of red cells at the base of the tube.
5. Add 100µl of Bovine Albumin 22% or 30% taking care not to distribute cell button.
6. Without mixing, re-incubate at 37°C for 15 – 30 minutes.
7. Examine for agglutination. Results may be read with either an optical aid or microscopically.

TECHNIQUE – ALBUMIN DISPLACEMENT METHOD

1. Follow steps 1 – 3 of the Albumin Replacement Method.
2. Upwardly displace the supernatant saline-serum mixture by carefully allowing one volume of NS Biotec 30% Serological 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 (pH6.9).
2. Into a glass tube dispense 100µl of serum or plasma and the 2-3% cell suspension.
3. Add 100µl of Bovine Albumin 22% or 30%.
4. Mix well and incubate at 37 °C for 15 – 60 minutes.
5. Centrifuge at 1000g for 30 seconds.
6. Resuspend the cell button and examine for signs of agglutination.
7. Record the results.

TECHNIQUE – INDIRECT ANTIGLOBULIN TEST

1. Prepare a 2-3% suspension of red cells in isotonic buffered saline (pH6.9).
2. Into a glass dispense 100µl of serum or plasma and the 2-3% cell suspension.
3. Add 100µl of Bovine Albumin 22% or 30%.
4. Wash the cells 3 – 4 times in isotonic buffered saline, pouring off all the saline after each wash.
5. Add 200µl of NS Biotec Anti-Human Globulin to the dry cell button.
6. Mix gently and centrifuge at 1000g for 15 seconds.
7. Examine for agglutination. Results may be read with either an optical aid or microscopically.
8. Record the results.
9. Confirm validity of all negative reactions by using IgG sensitized red cells

TECHNIQUE – ANTIBODY TITRATION PROCEDURE

1. Prepare doubling dilutions of test serum in either inert group AB Serum or 6% serological albumin. (The latter can be prepared by Mixing100µl NS Biotec 30% Serological Albumin with 400µl isotonic buffered saline.)
2. Prepare a 2% suspension of appropriate washed red cells in NS Biotec 22% and 30% Serological Albumin.
3. Add 100µl of 2% cell suspension to 100µl of each serum dilution, mix well and incubate at 37°C for 15 to 60 minutes.
4. Centrifuge at 1000g for 30 seconds.
5. Gently resuspend each cell button and examine for agglutination.
6. Record results.
7. An antiglobulin test may be performed on those cells showing weak or negative results.

STABILITY OF REACTIONS

1– All results should be read immediately and the results interpreted and recorded without delay.
2–Delays in reading or in the completion of washing steps, where appropriate may result in dissociation of antigen-antibody complexes, leading to false negative or weak positive reactions.

QUALITY CONTROL

1– The efficacy of bovine albumin reagents should be confirmed throughout their use.
2– Red cells sensitized with an autoantibody whether it be in vitro or in vivo may spontaneously agglutinate in concentrations of albumin as low as 6%. It is therefore important that control tests in which the red cells are mixed with the appropriate serological albumin solution alone are routinely set up.

LIMITATIONS

1. Serological albumin will not enhance the reactivity of all blood group antibodies.
2. Serological albumin should not be used as a negative control for Potentiated IgG blood grouping reagents.
3. False positive and false negative results may occur due to improper technique or contaminated test materials.

STABILITY DATA

* Kit components are stable to expiry if stored at 2°C to 8°C.
* Do not freeze or expose to elevated temperatures.

SPECIFIC PERFORMANCE CHARACTERISTICS

NS Biotec's 22% and 30% Serological Albumin solutions 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 possess the most frequently inherited blood group antigens.

NOTES

1–Marked turbidity may indicate reagent deterioration or contamination.
2–All serological Albumin Solutions are derived from accredited and inspected herds from areas where the risk of BSE (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 inactivate BSE-like agents.
3–Products of animal origin cannot be assumed to be free from

infectious agents, therefore appropriate care should be taken in the use and disposal of the container and its contents

BIBLIOGRAPHY

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	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

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