SBio Monospecific Coomb's Sera (IgG)

Polyclonal Anti-IgG antibodies for direct and indirect Coombs Test



+ 2°C + 2°C Store at 2-8°C	Manufacturer	IVD In vitro Diagnostic Medical Device	LOT Batch Number / Lot Number	Expiry date	EC REP Authorised Representative in the European Community
Consult Instructions for use	Date of Manufacture	REF Catalogue Number	This side up	Reagent Description of the reagent	Xn Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.

SUMMARY

Generally antibodies involved in transfusion reactions are of two types namely the complete and incomplete, whereas the complete antibodies agglutinate red cells in saline medium, the incomplete type of antibodies sensitizes red cells without agglutination.

In the direct antiglobulin tests, Anti-human globulin reagent is used to detect antibodies adsorbed to the red blood cells *in vivo*. After direct antiglobulin testing with a polyspecific reagent reveals globulins, Monospecific Coomb's Sera (IgG) is used to characterize the coating proteins.

In the indirect antiglobulin tests, Anti-human globulin reagent is used to detect antibodies adsorbed to red blood cells *in vitro*. Monospecific Coomb's Sera (IgG) is used in indirect antiglobulin testing to distinguish patterns of reactivity in a single serum containing complement binding and non-complement binding antibodies.

Monospecific Coomb's Sera (IgG) is useful for antibody detection, antibody identification and umbilical cord red blood testing.

REAGENT

Monospecific Coomb's Sera (IgG) is a ready to use reagent containing antibodies reactive with human gamma globulins. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and titre.

REAGENT STORAGE AND STABILITY

- 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 label.

PRINCIPLE

Normal human red blood cells, in presence of antibody directed towards the antigen they possess may fail to agglutinate and become sensitized. This may be due to the particular nature of antigen and antibody involved. SBio Monospecific Coomb's Sera (IgG) reagent would react with red cells sensitized with gamma globulins and cause agglutination of red blood cells.

NOTE

1. In vitro diagnostic reagent for laboratory and professional

use only. Not for medicinal use.

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- The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
- Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
- SBio Monospecific Coomb's Sera (IgG) is not from human source, hence contamination due to HBsAg and HIV is practically excluded.

SAMPLE COLLECTION AND STORAGE

No special preparation of patient is required prior to sample collection by approved techniques. Do not use haemolysed samples.

For Direct Antiglobulin Test

Blood drawn into EDTA is preferred but oxalated, citrated or clotted whole blood may be used. The blood sample should be tested as soon as possible after collection and should not be stored.

For Indirect Antiglobulin Test

Serum not more than 48 hours old should be used for testing purpose.

ADDITIONAL MATERIAL REQUIRED For Direct Antiglobulin Test

Test tubes (12 x 75 mm), Pasteur pipettes, centrifuge, isotonic

saline, Coombs control cells, optical aid.

For Indirect Antiglobulin Test

Test tubes (12 x 75 mm), Pasteur pipettes, centrifuge, Incubator (37°C), Isotonic saline, Bovine Serum albumin, Reagent red blood cells for antibody detection and antibody identification, Coombs control cells, optical aid.

PROCEDURE

Bring reagent to room temperature before testing.

- **Direct Antiglobulin Test**
- 1. Prepare a 5% suspension of red blood cells to be tested in isotonic saline.
- 2. Pipette one drop of the cell suspension into a test tube.
- 3. Fill the tube with fresh isotonic saline and centrifuge for 30 seconds at 3400 rpm (1000g).
- 4. Decant and repeat this washing atleast thrice.
- 5. Add two drops of SBio Monospecific Coomb's Sera (IgG)

and mix well.

- 6. Centrifuge for one minute at 1000 rpm (125 g) or for 20 seconds at 3400 rpm (1000 g).
- Very gently, resuspend the cell button observing for agglutination macroscopically.
- 8. To all negative results add one drop of Coombs control cells and observe for agglutination.

Indirect Antiglobulin Test for antibody identification

- 1. Prepare 5% suspension of reagent red blood cells to be tested in isotonic saline.
- 2. Pipette two drops of serum to be tested in an appropriately labelled test tube.
- 3. Pipette one drop of 5% reagent red blood cell suspension and mix well.
- If required, add two drops of Bovine serum albumin reagent and mix well and incubate at 37°C for fifteen minutes.
- 5. If enhancement medium is not being used, incubate the tube at 37°C for 30 minutes.
- After incubation wash the cells thoroughly with isotonic saline for minimum three times. Decant completely after last wash.
- Add two drops of SBio Monospecific Coomb's Sera (IgG) into the test tube containing the sedimented cells and mix well.
- 8. Centrifuge for one minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
- Very gently resuspend the cell button and observe for agglutination macroscopically.

INTERPRETATION OF RESULTS Direct Antiglobulin Test

Agglutination of red blood cells is a positive result and indicates presence of human IgG on the red blood cells. No agglutination is a negative test result and indicates absence of human IgG on red blood cells.

Indirect Antiglobulin Test

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Agglutination of red blood cells is a positive result and indicates presence of antibody against the antigen in the serum under test.

No agglutination of red blood cells is a negative result and indicates absence of antibody against the antigen in the serum under test.

REMARKS

- To all negative test results, after the antiglobulin test, one drop of Coombs control cells should be added. If Coombs control cells do not agglutinate then the test must be repeated.
- 2. Red blood cells showing a positive direct antiglobulin test cannot be used for the indirect antiglobulin test.
- It is recommended that Anti-IgG activity of Monospecific Coomb's Sera (IgG) be tested from time to time preferably on a daily basis using Coombs control cells as a positive control.
- 4. All glassware used in the test should be scrupulously clean dry and free from contamination with human serum.
- 5. Contaminated Bovine serum albumin, saline or glassware may inactivate Monospecific Coomb's Sera (IgG).
- Use of various drugs and certain diseases (such as megaloblastic anaemia) are known to be associated with a positive direct antiglobulin test.
- Cord cells obtained from a newbom exhibiting haemolytic disease of the newborn, especially due to ABO incompatibility may give false negative results.
- Monospecific Coomb's Sera (IgG) is free from Anti-T activity.
- As undercentrifugation or overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required for achieving the desired results.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Blood Transfusion in Clinical Medicine, PL Mollison, CP Engelfriet, Marcela Contreras, 9th Edition, 1994 Blackwell Science Publications. (2) AABB Technical Manual, 13th Edition, 1999. (3) HMSO, Guidelines for the Blood Transfusion Services, 2nd Edition, 1994.



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EC REP

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