

137 mm x 218 mm

**ERYBANK<sup>®</sup>**

**ANTI-HUMAN IgG MONOSPECIFIC COOMBS REAGENT FOR DIRECT AND INDIRECT ANTIGLOBULIN TEST**

**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, Anti-human IgG monospecific coombs reagent 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*. Anti-human IgG monospecific coombs reagent is used in indirect antiglobulin testing to distinguish patterns of reactivity in a single serum containing complement binding and non-complement binding antibodies.

Anti-human IgG monospecific coombs reagent is useful for antibody detection, antibody identification and umbilical cord red blood testing.

**REAGENT**

ERYBANK<sup>®</sup> Anti-human IgG monospecific Coombs reagent 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. ERYBANK<sup>®</sup> Anti-human IgG monospecific Coombs 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.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. ERYBANK<sup>®</sup> Anti-human IgG monospecific Coombs reagent 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, ERYBANK<sup>®</sup> 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 ERYBANK<sup>®</sup> Anti-human IgG monospecific Coombs reagent and mix well.
6. Centrifuge for one minute at 1000 rpm (125 g) or for 20 seconds at 3400 rpm (1000 g).
7. 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.
4. If required, add two drops of ERYBANK<sup>®</sup> 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.
6. After incubation wash the cells thoroughly with isotonic saline for minimum three times. Decant completely after last wash.
7. Add two drops of ERYBANK<sup>®</sup> Anti-human IgG monospecific Coombs reagent 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).
9. 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

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

1. 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.
3. It is recommended that Anti-IgG activity of Anti-human IgG monospecific Coombs reagent 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 Anti-human IgG monospecific Coombs reagent.
6. Use of various drugs and certain diseases (such as megaloblastic anaemia) are known to be associated with a positive direct antiglobulin test.
7. Cord cells obtained from a newborn exhibiting haemolytic disease of the newborn, especially due to ABO incompatibility may give false negative results.
8. ERYBANK<sup>®</sup> Anti-human IgG monospecific Coombs reagent is free from Anti-T activity.
9. 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. (4) Data on File: Tulip Diagnostics (P) Ltd.

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In vitro Diagnostic Reagent  
NOT FOR MEDICINAL USE  
Store at 2-8°C. DO NOT FREEZE.  
Preservative: 0.1% NaN<sub>3</sub>  
ISO 9001:2008, EN ISO 13485:2012