

Coombscell-E

IgG-coated Red Blood Cells for the control of the antiglobulin test

FOR IN-VITRO DIAGNOSTIC USE

For tube test

Package size

[REF] 816030100 [VOL] 10 mL Coombscell-E

Intended Use

Coombscell-E Red Blood Cells are used for

- in-house quality control (reactivity control of Anti-Human-Globulin)
- to control the technique of antiglobulin-test with negative results to verify the negative results of the IAT (Indirect Antiglobulin Test) and DAT (Direct Antiglobulin Test)

Summary

Moreschi first described the use of Anti-Human Globulin in 1908¹. Coombs rediscovered the test in 1945.^{2,3} By injecting rabbits with human IgG, they were able to produce a protein (Anti-IgG) that reacted with incomplete antibodies (IgG). Most "incomplete" antibodies (IgG) fail to agglutinate red blood cells suspended in saline.⁴ Most clinically significant antibodies in red blood cell serology are of the IgG class and can only be detected by the use of Anti-IgG. A stable lattice structure is formed and agglutination occurs when Anti-IgG binds to the IgG sensitized red blood cells.

Biotest Anti-Human Globulin reagents are used to test for the presence or absence of unexpected red blood cell antibodies. Furthermore, blood group antigen typing (with the corresponding test reagent for the indirect antiglobulin-test) can be carried out. Routine pretransfusion studies always include tests for antibody screening, crossmatch and antibody identification.

Principle of the Test

The test principle is a hemagglutination test. Anti-Human Globulin reacts with IgG-coated red blood cells of Coombscell-E. This leads to agglutination of red blood cells and verifies the negative results of the IAT (Indirect Antiglobulin Test) and DAT (Direct Antiglobulin Test).

Reagent

Coombscell-E is a single vial of group 0 red blood cells sensitized with human monoclonal IgG antibodies (specificity anti-D). Coombscell-E is suspended approx. 3 % in a modified Alsevers solution and can be used immediately after re-suspension.

Preservative: 0.01% Neomycin, 0.033% Chloramphenicol, 5 ppm Amphotericin B

After opening the vial the product can be stored under proper storage conditions (2 to 8°C) until the expiry date.

- No U.S. Standard of Potency
- For In-vitro Diagnostics use
- Use as furnished, do not dilute

Precautions

- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use damaged vials.
- Do not use if markedly hemolyzed, slight hemolysis before the expiry date does not effect the reactivity
- Handle and dispose of reagents as potentially infectious
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DEFIVED WAS FOUND NEGATIVE WHEN TESTED WITH FDA LICENSED EIA/ELISA TESTS. NAT TESTING WAS NOT PERFORMED. NO KNOWN TEST METHOD CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
- Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.

Specimen collection

Fresh samples of clotted or EDTA anticoagulated whole blood can be used for the indirect antiglobulin test. EDTA anticoagulated whole blood samples must be used for the direct antiglobulin test. EDTA or citrate anticoagulated whole blood samples must be used for the crossmatch. Samples collected following standard blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. Use of samples older than ten days should be avoided unless there is no other alternative since antibody reactivity has been shown to decrease in older samples. If testing is delayed, EDTA and clotted specimens should be stored at 2 to 8°C, citrated specimens (donor segments) at 1 to 6°C. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor unit. These red blood cells to be tested must be prepared prior to testing. Refer to instructions in the TANGO® optimo Users Guide⁴. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used.

Materials

Materials supplied

Coombscell-E

Material required but not provided

- Pipettes (drop volume 40 to 50 µL)

- Isotonic saline solution

Coombscell-E is a single vial of group 0 red blood cells sensitized with human monoclonal IgG antibodies (specificity anti-D).

- Reagent Red Blood Cells: Biotest: Biotestcell® 1 & 2 [REF] 816014100, Biotestcell® 3 [REF] 816085100, Biotestcell®-I 8 [REF] 816020100, Biotestcell®-I 11 [REF] 816021100
- Donor or patient red blood cells
- MLB 2 (Modified LISS Biotest) [REF] 8065200100
- Anti-Human Globulin Anti-IgG [REF] 804175100
- Anti-Human Globulin Anti-IgG, -C3d Polyspecific [REF] 804115100
- Glass tubes 10 x 75mm or 12 x 75mm
- Serological centrifuge
- Interval Timer
- Markers
- Optical aid (optional). The use of an optical aid for agglutination reading must be validated by the user.

Test procedure

A. Tube test

Verification of negative result in antiglobulin test

1. Add 1 drop Coombscell-E to each negative result of the indirect or direct antiglobulin test performed.
2. Centrifuge for at 20 seconds 800-1000 x g.
3. Gently dislodge the cell button and observe for agglutination.
4. Record results.

Stability of the Reaction

Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Time delays may cause a dissociation of the antigen-antibody complexes resulting to false negative or more often weak positive reactions.

Quality Control

The reactivity of all reagents should be confirmed by testing with known positive and negative red blood cells on each day of use.

To confirm the reactivity or specificity of Biotest Anti-Human Globulin Anti-IgG and Anti-Human Globulin Anti-IgG, -C3d Polyspecific the reagent should be tested with IgG coated and non coated red blood cells respectively. The reagent is satisfactory for use if it reacts only with the IgG coated red blood cells (Coombscell-E).

Negative results in an antiglobulin test should be verified with IgG coated red blood cells:

Add 1 drop of IgG coated red blood cells, mix and centrifuge for 20 seconds at 800 - 1000 x g.

Positive result: The negative reaction in the indirect antiglobulin test is valid, reactive Anti-Human Globulin is present.

Negative result: A technical error was made and the test must be repeated.

It is recommended that a positive and a negative control be performed in parallel with testing.

Interpretation of results

Tube test

Agglutination: The Anti-Human Globulin is reactive; the indirect and direct antiglobulin technique performed is valid.

No agglutination: The Anti-Human Globulin is non-reactive; the technique performed was invalid (e.g. insufficient washing).

An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technical Manual, 15th edition).

Limitations

- Insufficient or inappropriate washing can lead to false negative or false positive reactions. Small amounts of residual patient sera/plasma can neutralize the Anti-Human Globulin Anti-IgG or Anti-Human Globulin Anti-IgG, -C3d Polyspecific.
- False positive or negative results may occur due to bacterial contamination of the IgG coated red blood cells or improper centrifugation.
- Some conditions that may cause false positive results are:
 - Contamination of sample or reagents
 - Improper storage or preparation of red blood cells
- Incorrect incubation
- Incorrect calibration / centrifugation
- Incorrect reading technique

In case of unclear results with unknown causes, contact Biotest Diagnostics Corporation at 800-522-0090.

Specific Performance Characteristics

The final release testing is performed according to the product specific SOPs. Each lot of Biotest Coombscell-E reagent is tested in the Quality control by package insert method against to insure suitable reactivity.

For the product performance it is necessary to adhere to the recommended method in the instructions for use

For Technical Support or further product information, contact Biotest Diagnostics Corporation at 800-522-0090.

Note

Techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user. Used test material must be discarded as hazardous material. Waste management according to national guidelines.

FOR REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each product.

Glossary of Symbols

Symbol	Definition	Symbol	Definition
LOT	Batch Code	IVD	<i>In vitro</i> diagnostic medical device
⚠	Caution, consult accompanying documents	📖	Consult instructions for use.
🏭	Manufacturer	🕒	Use by YYYY-MM-DD
▽	Contains sufficient quantity for <n> tests.	REF	Catalog number
🌡	Temperature limitation		

Bibliography

1. Moreschi C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Bakt 1908; 46:49,456
2. Coombs, RRA, Mourant, AE and Race, RR: "A new test for the detection of weak and "incomplete" Rh agglutinins." Br J Exp Pathol 26:255, 1945
3. Coombs, RRA, Mourant AE and Race, RR: "In vivo isosensitization of red blood cells in babies with hemolytic disease." Lancet i: 264, 1946
4. Pittiglio, D. Harmening. Modern Blood Banking and Transfusion Practices. Philadelphia, PA: F.A. Davis, 1983.
5. Mark E. Brecher, MD et al. Technical Manual 15th Edition, Bethesda, MA: AABB, 2005

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