EN

Coombscell-E

IgG-coated reagent red blood cells for the control of the antiglobulin-test

REF 816 030

VOL 10 ml

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

IVD Diagnostic reagent for in vitro use only
To be used by trained laboratory personnel only.

Test purpose
Coombscell-E reagent red cells are used for
- in-house quality control (reactivity control of anti-human-globulin)
- to control the technique of antiglobulin-test with negative results

Test principle
The test principle is a hemagglutination test or solid phase test with Solidscreen™ II. Anti-human-globulin reacts with the IgG antibodies coating the reagent red blood cells of Coombscell-E. This leads in the tube test to agglutination of red cells and in the solid phase test with Solidscreen™ II a layer of cells across the bottom of the wells will be observed.

Reagent
Coombscell-E are sensitized with IgG antibodies. Coombscell-E is suspended approximately 3 % in a modified Alsevers solution and can be used immediately after cautious resuspension.

Material needed but not supplied
- Test red cells for the detection of antibodies (e.g. Biotestcell®)
- Pipettes (drop volume 40-50 µl)
- Isotonic saline solution
- Anti-human globulin (e.g. Anti-Human-Globulin Color REF 804 120, 804 115 and 804 130)
- Glass tubes
- Laboratory centrifuge

Sample material
Fresh serum or plasma collected following general blood sampling guidelines are acceptable.

Test procedure
A. Tube test
Control of the anti-human-globulin
1. Mix 2 drops anti-human-globulin and 1 drop Coombscell-E in a test tube.
2. Centrifuge for 2 minutes at 150-200 x g or 20 seconds at 800-1000 x g.
3. Gently dislodge the cell button and observe for agglutination.

Technical performance control of antiglobulin-test with negative result
1. Add 1 drop Coombscell-E to each negative antiglobulin-test.
2. Centrifuge for 2 minutes at 150-200 x g or 20 seconds at 800-1000 x g.
3. Gently dislodge the cell button and observe for agglutination.

B. Solidscreen™ II
For the exact test procedure as well as to the reaction pattern please refer to the detailed instructions for use of Solidscreen™ II Strip (REF 806 521).

Interpretation of results
A. Tube test
Agglutination: The anti-human-globulin is reactive; the technique performed is valid.
No agglutination: The anti-human-globulin is non-reactive; the technique performed was invalid (e.g. insufficient washing).

Evaluation of the reaction strength is carried out according to the Technical Manual (1):

Reaction strength	Agglutination
4+	One solid agglutinate
3+	Several large agglutinates
2+	Medium-size agglutinates, clear background
1+	Small agglutinates turbid background
+/-	Barely visible agglutination, turbid background
-	No agglutination

B. Solidscreen™ II
For the exact test procedure as well as to the reaction pattern please refer to the detailed instructions for use Solidscreen™ II Strip (REF 806 521).

Shelf life
After opening the vial the product can be stored under proper storage conditions (2...8°C) until the expiry date. The expiry date is printed on the label. Slight hemolysis before the expiry date does not effect the reactivity.
Do not use damaged vials.

Performance characteristics and limitations of the method
- When using Coombscell-E in solid phase test Solidscreen™ II strictly adhere to the instructions for test procedure. Failure to do so may result in forming of agglutination instead of carpeting of cells.
- The reactivity of the product may decrease during the dating period. The rate of decrease in reactivity is partially dependent on individual donor characteristics that are neither controlled nor predicted by the manufacturer.

In case of unclear results with unknown causes, our Bio-Rad Service (phone: +49-6103-3130-611) will assist you.

Warning and precautions
- Do not use damaged vials.
- Do not use if discolored or markedly hemolyzed, slight hemolysis before the expiry date does not affect the reactivity.
- Discoloration or other visible changes may indicate a bacterial contamination. In this case the reagent must be discarded. The cause for turbidity must be examined by the manufacturer.
- Manual 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 information can be found in the safety data sheet.
- Source material from which this product was derived was found negative for anti-HIV-1/-2, anti-HCV, HBsAg and anti-Lues. Nevertheless, all blood products must be regarded as potentially infectious and appropriate safety precautions are recommended.
- The packaging of this product contains natural rubber latex which may cause allergic reactions.
- Internal quality controls according to national guidelines are recommended at regular intervals.
- Consult **downloads.bio-rad.com** to download the valid version of this instruction for use.

Coombscell-E is produced every 4 weeks.

Glossary of Symbols

⚠	Consult the warnings and precautions

References
(1) Technical Manual, 17th edition, Section 1, American Association of Blood Banks

Key: Underline = Addition or significant change ◄= Deletion of text

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