



Coombs Control Cells

*For use in quality control of
anti-human globulin procedures*

For in vitro diagnostic use

Summary and Principle

Erythrocytes sensitized with human serum globulins are used as the positive controls in anti-globulin testing. Erythrocytes sensitized with human IgG should be used with anti-human globulins containing anti-IgG. The binding of anti-IgG in an anti-human globulin to IgG molecules attached to red cells results in agglutination.

Agglutination of the IgG-sensitized erythrocytes indicates that the anti-human globulin has been added and that its anti-IgG component is active.

Reagent

Coombs Control Cells: group 0 human erythrocytes sensitized with human IgG, provided as a $3\pm 1\%$ suspension in a buffered isotonic medium with neomycin and chloramphenicol as preservatives. Store at 2–8°C.

Do not freeze.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The pipette of the vial contains natural rubber latex which may cause allergic reactions.

Ready to use. **Do not wash Coombs Control Cells before use.** Indication of deterioration: notable hemolysis and/or turbidity which may be caused by microbial contamination or improper handling.

Procedure

Reagent Provided

Coombs Control Cells (070205)

Materials Required but Not Provided

1. Anti-human globulin(s)
 - a. Anti-IgG, -C3d; polyspecific
 - b. Anti-IgG (heavy chains)
2. Centrifuge calibrated for 1000 rcf or 150 rcf (Immufuge® III or DAC III)

Procedure Outline

1. Gently resuspend Coombs Control Cells by repeated inversion of the vial.
2. After examining antiglobulin tests for agglutination, add 1 drop of Coombs Control Cells to each negative or questionable reaction.

3. Shake tubes gently to mix reagents and centrifuge for 20 seconds at approximately 1000 rcf* or 1 minute at approximately 150 rcf*.
4. Gently resuspend cells and examine immediately for macroscopic agglutination.
Record Results.
Interpretation: Positive - Cells agglutinated 1+ or greater.
Negative or questionable - Cells not agglutinated or cells agglutinated less than 1+.

Results

Agglutination of the Coombs Control Cells indicates that anti-human globulin was added and that its anti-IgG component was active. Therefore, if performed properly, the original antiglobulin test is valid. Very weak agglutination of the Coombs Control Cells may be due to an insufficiently reactive anti-human globulin or inadequate washing of test cells. The original antiglobulin test may be invalid and should be repeated.

No agglutination of the Coombs Control Cells usually indicates that the test cells were inadequately washed, that anti-human globulin was omitted from the test or that the anti-IgG in the serum was accidentally neutralized. The original antiglobulin test is, therefore, invalid and should be repeated.

Limitation of Procedure

Anti-human globulin lacking antibodies to human IgG will not react with Coombs Control Cells.

False negative results may occur if

1. Coombs Control Cells are stored improperly and lose reactivity.
2. Cells are improperly centrifuged.
3. Resuspension technique is too vigorous to preserve agglutination.

False positive results may occur if

1. Coombs Control Cells or anti-human globulins have microbial contamination.
2. Tests are improperly centrifuged.

Specific Performance Characteristics

Each lot of Coombs Control Cells is carefully sensitized and standardized to provide a positive agglutination control for anti-human globulins containing anti-IgG when used as outlined in the procedure described. Sufficient testing is performed on each lot of material to assure its reactivity throughout the dating period.

Bibliography

1. Stratton, F.; Renton. P.H. Practical blood grouping, Springfield: Charles C. Thomas; 1958: 181-182.
2. Technical manual of the American Association of Blood Banks. 10th Edition: 1990: 477.

Warranty

This product is warranted to perform as described in its labeling and in the product literature, and Medion Diagnostics AG disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event shall Medion Diagnostics AG be liable for any consequential damages arising out of the aforesaid express warranty.