Complement Control Cells

CONTROL +

For Confirmation of Anti-C3 Reactivity

- IVD
- **Rx ONLY**
- 1°C – 10°C
- Do Not Freeze
- Discard if markedly hemolyzed
- 2-4% Suspension
- No US standard of potency
- Preservatives: chloramphenicol (0.25mg/mL) neomycin sulfate (0.1 mg/mL) gentamycin sulfate (0.05 mg/mL)

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

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IMMUCOR

Intended Use:
Complement Control Cells are intended for use in confirming reactivity of the anti-C3 component of Anti-Human Globulin.

Summary of the Test:
The Antiglobulin (Coombs) Test, when performed correctly, is a highly sensitive method for the detection of human globulin bound to red blood cells, whether in vivo or following incubation with serum or plasma in vitro. Depending upon the specificity of the Anti-Human Globulin used, a positive reaction may be due to sensitization of the test red blood cells with immunoglobulin (IgG), with complement (C'), or with both.

Principle of the Test:
Red blood cells coated with C3b (C3c/C3d), are added directly to Anti-Human Globulin, centrifuged and read for macroscopic agglutination. The presence of macroscopic agglutination indicates that active anti-C3 reactivity is present in the test system and that neutralization of the Anti-Human Globulin has not occurred.

Reagents:
Complement Control Cells are prepared from whole blood using a cold low-ionic-strength procedure, as described by Fruitstone.[1] Following sensitization with C3b (C3c/C3d), the cells are washed to remove unbound protein, then resuspended to a concentration of 2-4% in a buffered preservative solution containing adenosine and adenine to retard hemolysis and/or loss of antigenicity during the dating period. Chloramphenicol (0.25 mg/ml), neomycin sulfate (0.1 mg/ml), and gentamycin sulfate (0.05 mg/ml) are added as preservatives.

Precautions:
For in-vitro diagnostic use. No US standard of potency. Store at 1 to 10 C when not in use. Effort should be made to minimize contamination during use. Do not freeze. Do not use if markedly hemolyzed. This reagent is to be used as supplied. Do not dilute. Do not use past the expiration date. Do not use leaking vials. Do not use unlabeled vials.

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 PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

Handle and dispose of reagent as if potentially infectious.

The format for the expiration date is expressed as CCYY-MM-DD (year-month-day).

Procedure:
Materials Provided:
Immucor Complement Control Cells.

Additional Materials Required:
1. 10 x 75mm or 12 x75mm test tubes and a test tube rack
2. Anti-Human Globulin containing anti-C3
3. Serologic centrifuge*
4. Interval timer
5. Marking pen

* It is the user's responsibility to validate an accessory device (either listed or otherwise) for its intended use. Validation results should be maintained as part of the laboratory's records for review by regulatory agencies.

Test Method:
1. Add 1 drop of Immucor Complement Control Cells to a negative Direct Antiglobulin Test performed with anti-C3 **–or–** add 1 drop of Immucor Complement Control Cells to a tube containing 1 or 2 drops of Anti-Human Globulin (containing anti-C3), for quality control of the reagent.
2. Mix well. NOTE: Manufacturers of Anti-Human Globulin containing an anti-C3 component generally recommend a period of delay (e.g. approximately 5 minutes) at room temperature before centrifuging the test mixture, in order to enhance weak anti-complement reactions. Refer to the Manufacturer's Directions for use of the Anti-Human Globulin reagent.
3. Centrifuge according to the manufacturer's directions for the Anti-Human Globulin used.
4. Resuspend the red blood cells by gentle shaking and examine for macroscopic agglutination. Record result of the control test.

Stability of Reaction:
Test and control results should be interpreted immediately upon completion of the test.

Interpretation of Results:
POSITIVE: Macroscopic agglutination of Complement Control Cells indicates the presence of active anti-C3b and/or anti-C3d in the test system. NOTE: Agglutination by anti-complement is seldom as strong as that customarily seen with anti-IgG and is more readily dispersed.

NEGATIVE: No agglutination of Complement Control Cells may indicate the omission or possible partial inactivation of the Anti-Human Globulin reagent.

NOTE: A negative test obtained with Complement Control Cells may also be encountered if the Anti-Human Globulin reagent used does not contain adequate anti-C3 activity. Polyspecific Anti-Human Globulin reagents that do not contain anti-C3d may be unsuitable for use in Direct Antiglobulin Test Procedures.

Limitations:
1. The control testing does not provide absolute assurance that false results will not occur in the performance of direct antiglobulin tests. Errors resulting from improper resuspension, improper incubation, etc., may still occur and go undetected.
2. Agglutination is expected to occur with Anti-C3d reagents because C3d is a component of C3b and is therefore present on red blood cells coated with C3b. Some Anti-C3d reagents of monoclonal origin, however, may be directed at epitopes that are concealed when the C3b molecule is still intact (i.e. before C3c has been cleaved away).[2] In such cases, weaker or no agglutination may be observed when Immucor Complement Control Cells are added to the test system. The product may not be suitable for controlling the test with this type of Anti-C3d.
3. The reactivity of Immucor Complement Control Cells may diminish over the dating period. The rate at which reactivity (i.e., agglutinability) is lost is partially dependent upon the storage of the reagent. This cannot be controlled or predicted by the manufacturer.

Specific Performance Characteristics:
Each lot of Immucor Complement Control Cells is tested with Anti-Human Globulin of relevant specificity to assure that the cells are coated with the appropriate protein. The performance of this product is dependent on adhering to the recommended methods found in this insert. For additional information or for technical support, contact Immucor at 855-IMMUCOR (466-8267).

Bibliography:
1. Fruitstone MJ. C3b sensitized erythrocytes. Transfusion 1978; 18:125
2. Lachmann PJ, Pangburn MK, Oldroyd RG. Breakdown of C3 after complement activation. J Exp Med 1982:156:205-216

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Key:
Underline = Addition or significant change; ▲ = Deletion of text