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HBS - C3 Control Cells

Intended Use:

Hemo bioscience C3 Control Cells are used to confirm the reactivity of anti-C3 in Anti-Human Globulin.

Summary and Explanation:

The Antiglobulin Test detects human globulin bound to red blood cells. The Direct Antiglobuiln Test detects globulin bound in vivo as may occur in Hemolytic Disease of the Fetus and Newborn (HDFN), transfusion reactions, and autoimmune hemolytic anemia. Certain drugs are also known to activate complement and can coat the cells in vivo. The Indirect Antiglobulin Test (IAT) is a two phase test used to detect the presence of serum immunoglobulins bound in vitro. The DAT and IAT typically detect IgG or complement or both depending on the specificity of the Anti-Human Globulin (AHG) reagent used. Under appropriate test conditions AHG reagents containing anti-C3 will agglutinate red blood cells sensitized with the C3 component of complement. It is important to use a control to confirm the efficacy of the AHG reagent used**.**

Principle of the Procedure:

Hemo bioscience C3 Control Cells are added to negative tests, centrifuged and read. Agglutination of the C3 Control Cells indicates that active anti-C3 reagent is still present, the washing process was successful and anti C3 reagent was added. A negative result after the addition of C3 Control Cells indicates either insufficient anti-C3 reagent was added or the anti-C3 reagent may have been neutralized.

Reagent Description:

C3 Control Cells are prepared by coating human red blood cells with C3b (C3c/C3d) using a modified Fruitstone[1] method. These red blood cells are supplied as a 3-5% suspension in a preservative solution. containing chloramphenicol (0.34g/L), neomycin sulfate (0.1g/L) and levofloxacin (0. 12 g/L).. The format for the expiration date is expressed as YYYY-MM-DD..

Precautions:

1. This reagent should contains human source material and should be handled and disposed of as if it is potentially infectious. Source material has been tested in accordance with FDA requirements and found negative.
2. Control cells are for *in vitro* diagnostic use only and are supplied ready for use, no dilution or modification is required.
3. This reagent is designed to be used by operators trained in serological techniques.
4. Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

Storage:

The reagent should be stored at 2-8°C when not in use. Do not freeze or expose to elevated temperatures as improper storage may cause loss of reactivity. Do not use if markedly hemolyzed. Avoid contamination during use.

Re-suspend each vial of C3 Control Cells prior to use by gentle inversion.

Procedure:

Materials Provided

Hemo bioscience C3 Control cells

Materials Required But Not Provided

Test Tubes and test tube rack
Centrifuge (1000 rcf)
Pipettes
Timer
Anti-Human Globulin (AHG) reagent containing anti-C3

Recommended Techniques:

Conventional Tube Testing

1. Add one drop of C3 Control Cells to a negative Antiglobulin Test performed with an AHG reagent containing anti-C3.
   OR
   Add one drop of C3 Control Cells to a tube containing 1 or 2 drops of AHG reagent containing anti-C3.
2. Mix well and centrifuge according to the Instructions for Use for the antiglobulin reagent in use.
3. Gently agitate the tube using a tip and roll technique to dislodge the red cells and immediately examine macroscopically for agglutination. Following centrifugation, tests should be read immediately and results should be interpreted without delay. Delays may result in the agglutination being dispersed.
4. If the C3 control cells show a negative reaction after step 3, re-suspend the contents of the tube and incubate at room temperature for 5 minutes (+/- 1 minute) then repeat steps 2 and 3. Weak complement/anti-complement reactions may be enhanced by a short incubation at room temperature.

Interpretation of Results:

Positive Test

Macroscopic agglutination of the red blood cells with a reaction strength of + or greater indicates the presence of active anti-C3b and/or anti-C3d in the test system. C3 Control Cell agglutination by anti-complement will show as a mixed field reaction, is rarely as strong as that seen with anti-IgG and is easily dispersed.

Negative Test

No agglutination of the red blood cells indicates the omission or possible inactivation of the AHG reagent. A negative test may also indicate that the AHG reagent used does not contain adequate anti-C3 activity.

Gel/Column Agglutination Technology IAGT Technique

The use of HBS-C3 Control Cells have been evaluated and found suitable for testing in the Ortho ID-MTS Gel Technology System. Follow the procedure for Direct Antiglobulin Testing and interpretation of results contained in the manufacturer's Instructions for Use. Use of other gel or column agglutination technology systems must be validated by the user.

Limitations:

1. Over centrifugation can cause difficulty in re-suspending the red cells leading to rapid dispersal of agglutinates and weakened reactions.
2. False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents or samples and certain disease states.
3. Reactivity of HBS-C3 Control Cells may diminish over the dating period. Failure to store the reagents at 2-8°C when not in use may accelerate reagent deterioration.
4. HBS-C3 Control Cells may demonstrate weak to negative reactivity with anti-C3d when tested by the conventional tube method. This product may not be suitable for controlling anti-C3d by conventional tube testing.

Specific Performance Characteristics:

C3 Control Cells have been manufactured to provide a standardized control for the antiglobulin test. Each lot is tested to assure appropriate reactivity when used by the recommended test procedure. No U.S. standard of potency.

For Technical Support, contact Hemo bioscience at 1-866-332-2835.

Bibliography:

1. Fruitstone, M.J. C3b sensitized erythrocytes. Transfusion 1978; 18:125.
2. Lachman PJ, Pangbum MK, Oldroyd RG. Breakdown of C3 after complement activation. J Exp. Med 1982; 156:205-216.
3. Roback, J.D., ed. Technical Manual. 17th ed. Bethesda, MD: AABB, 2011.

Glossary of Symbols

Symbol	Definition
	Batch code
	Manufacturer
	Temperature limitation
	Consult instructions for use.
	Use by YYYY-MM-DD
	For *in vitro* diagnostic use