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 Antiglobulin Test detects globulin bound in vivo as may occur in Hemolytic Disease of the Fetus and Newborn (HDN), 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 Fusatone 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 contain 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. The packaging of this product contains dry natural rubber.

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

Conventional Tube Testing
1. Add one drop of C3 Control Cells to a negative Antiglobulin Test performed with an AHG reagent containing anti-C3.

2. Add one drop of C3 Control Cells to a tube containing 1 or 2 drops of AHG reagent containing anti-C3.

3. Mix well and centrifuge according to the Instructions for Use for the antiglobulin reagent in use.

4. 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.

5. 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.

Bibliography:

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