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Hemo-QC

Intended Use:

Hemo-QC simulates blood samples and is intended for the daily quality control of routine blood bank reagents used in manual, semi-automated and automated blood typing and antibody screening test systems.

Summary and Explanation:

The quality and efficacy of blood bank reagents can be adversely affected by improper storage and shipping conditions and bacterial or other contamination. Reagent deterioration can result in a loss or weakening of reactivity. It is necessary that laboratories perform appropriate daily testing to assure reagent performance.

Principle of the Procedure:

Hemo-QC is used to confirm the correct performance of ABO, RhD typing and antibody detection reagents. Additionally, Hemo-QC assists with evaluating the performance of anti-human globulin serum containing anti-IgG. When expected results are obtained with Hemo-QC the blood bank reagent under evaluation is performing acceptably. If unexpected results are observed, the problem may be due to an improper test procedure, faulty equipment and/or the contamination or deterioration of reagents.

Reagent Description:

Hemo-QC is supplied as a set of three tubes, each containing a 15% ± 2 suspension of red blood cells in a preservative diluent containing bovine serum albumin (51 g/L) to simulate the protein concentration of human serum. Chloramphenicol (0.34g/L), neomycin sulfate (0.1g/L) and levofloxacin (0. 12 g/L) are added as preservatives. The product contains the appropriate ABO and Rh(D) blood group antigens as well as corresponding ABO blood group antibodies and anti-D and anti-Fy^a. Each sample has a negative direct antiglobulin test. The three tubes are labeled as QC1 (green), QC2 (red), and QC3 (blue) with an eye readable identifier and a bar code.. The format for the expiration date is YYYY-MM-DD. The vial label and corresponding closure cap are color coded to prevent cross contamination.

TUBE	Specification
1 Green	Group AsubB RhD positive
2 Red	Group O RhD positive R1r DCcee with Anti Fy^a
3 Blue	Group A1 RhD negative rr ccee with Anti D

Precautions:

1. This reagent 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. The source of bovine albumin is either USDA approved or from sources where origin information is available. The donor animals have been inspected and certified disease free and are deemed to have a low TSE (Transmissible Spongiform Encephalopathy) risk.
3. Slight hemolysis may be observed; however, do not use the product if grossly discolored or hemolyzed.
4. This reagent is designed for use by operators trained in serological techniques.
5. Hemo-QC is for in vitro diagnostic use only as a quality control product for evaluating the performance of blood bank reagents.

Storage

Store the opened and unopened product at 2-8°C. Opened vials of reagent have a ten day expiration date. For unopened vials, do not use beyond the expiration date printed on the label. Allow to equilibrate to room temperature immediately prior to use. Refrigerate at 2-8°C immediately after use.

Failure to store the product at the correct temperature may result in accelerated loss of reagent performance.

Procedure:

Materials Provided

Hemo-QC

Materials Required But Not Provided

Routine Blood Bank reagents

Recommended Technique:

1. This product requires centrifugation prior to use. Perform centrifugation according to facility standard laboratory practice for the centrifugation of patient samples.
2. When using automated/semi-automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer.
3. For use in a manual system, follow the reagent manufacturer's Instructions for Use.
4. To prevent cross-contamination, care should be taken to match the color-coded closure cap to the corresponding tube.

Interpretation of Results:

Positive test

Agglutination of red cells

Negative test

No agglutination of red cells

TUBE	Anti-A	Anti-A1	Anti-B	Anti-A, B	Anti-D	A cells	B cells	SC/ID
1	+	0	+	+	+	0	0	0
2	0	0	0	0	+	+	+	+*
3	+	+	0	+	0	0	+	+*

*SC/ID – Antibody Screening Cells/Antibody Identification Panel – reactions of individual screening or panel cells is dependent on their antigenic profile.

Limitations:

1. False negative or positive reactions can occur due to contamination, improper storage, improper test performance or failure to add reagents. The cause(s) of a failure should be investigated and resolved.
2. Reaction strength using the same method and lot of red cells and anti-sera should be comparable. A significant decrease in the reaction strength should be investigated.

Specific Performance Characteristics:

Hemo-QC is manufactured to provide a standardized method to perform the quality control of blood bank reagents. Each lot is tested prior to release to ensure appropriate reactivity when used by recommended test methods.

No FDA standard of potency exists for this product.

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

Bibliography:

1. Roback, J.D., ed. Technical Manual. 17th ed. Bethesda, MD: AABB, 2011.
2. Centers for Medicare and Medicaid Service; Code of Federal Regulations, Title 42. U.S. Government Printing Office, Washington, DC, revised annually.

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