**corQC® Test System**

**For quality control of blood bank reagents**

- **IVD Rx ONLY**
- **1°C to 10°C**
- Do not use if Antiserum is turbid
- Do not use if cells are hemolyzed
- Red Blood Cells Preservatives: chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL), gentamycin sulfate (0.05 mg/mL)

**CAUTION:** Do NOT pipette this product by mouth, as the absence of murine virus has not been determined. All blood products should be treated as potentially infectious. The packaging of this product (dropper bulbs) contains dry natural rubber.

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**Intended Use:**
corQC Test System is used for the daily quality control evaluation of routine blood bank reagents.

**Summary of the Test:**
Blood grouping reagents, Anti-Human Globulin and Reagent Red Blood Cells are extensively tested by their manufacturer during production to show that they meet or exceed minimum potency, specificity and reactivity standards established by the Food and Drug Administration (FDA). Subsequent to manufacture, the performance of these reagents may be altered through inappropriate shipping or storage conditions, microbial or chemical contamination. Alterations leading to reagent deterioration, ie, loss of potency or antigen strength, manifest themselves as a weakening or loss of test reactions. Hence, laboratories must ensure that serologic test reagents are suitably reactive each day of use. corQC Reagents are used to evaluate the reactivity of routine blood bank reagents (eg, ABO reagents, Anti-D, Rh-Hr Control, Reagent Red Blood Cells, Anti-human Globulin, etc.) on a daily basis.

**Principle of the Test:**
Group AB, D+ red blood cells are used to prepare corQC Reagent Cells. They are used to evaluate the performance of Anti-A, Anti-B, Anti-A, B, Anti-D and Rh-Hr Control. corQC Reagent Antiserum contains weakly reactive monoclonal and polyclonal antibodies. It is used to evaluate serum (reverse) grouping red blood cells and antibody detection red blood cells. corQC Reagent Antiserum also assists in monitoring the performance of potentiation and Anti-Human Globulin (anti-IgG component). corQC Reagent Cells and corQC Reagent Antiserum should produce readily visible agglutination reactions with the reagents under test. No agglutination indicates reagent deterioration or technique failure.

**Reagents:**
corQC Reagent Cells: group AB, D+. The red blood cells have been prepared as a 2-4% suspension in a buffered preservative solution containing adenosine and adenosine to retard hemolysis and 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.

corQC Reagent Antiserum: A blend of polyclonal monoclonal (murine/human) antibodies diluted with bovine albumin in physiologic saline is used to simulate the protein concentration of human serum. The albumin used may, or may not, contain sodium caprylate. It is sourced from donor animals of United States origin that have been inspected and certified by USDA Food Safety and Inspection Service inspectors to be disease-free. This ruminant-based product is deemed to have low-TSE (Transmissible Spongiform Encephalopathy) risk. The reagent is to be used as supplied. Sodium azide (0.1% final concentration) is added to this reagent as a preservative.

corQC Data Sheets: to record daily QC test results.

**Precautions:**
For in vitro diagnostic use.

Store at 1-10°C when not in use. Do not freeze or expose to elevated temperatures. Do not use beyond expiration date. **Opened vials of Antiserum should be used within 6 months.** corQC Reagent Antiserum may become slightly turbid with age. Do not use the Antiserum if it is markedly turbid or if corQC Reagent Cells are notably hemolyzed. Do not use unlabeled vials.

Handle and dispose of the reagents as if potentially infectious.

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**Key:**
Underline = Addition or significant change; ▲ = Deletion of text
3. Add 1 drop of each reagent to the appropriate tubes labeled in step 2. In addition, add 1 drop of Anti-A or Anti-B to tube 13 and 1-2 drops of Anti-Human Globulin to tube 14.

4. Add 1 drop corQC Reagent Cells to tubes numbered 1-5.

5. Add 1 drop of serum grouping red blood cells (A, A, B, or O) to tube number 6. (Referencells Serum Grouping Cells are D-. If Referencells are not used, substitute any other reagent D- red blood cell sample, such as a screening or panel red blood cell.)

6. Add 1 drop of corQC Antiserum to tubes numbered 7-12. Do not add corQC Antiserum to tubes numbered 13 and 14.

7. Centrifuge tubes 1-9 and 14. Gently suspend each red blood cell button and examine for agglutination. Record results on the corQC Data Sheet.

8. Discard tubes 1-5, 7-9 and 14. Save tube 6 for further testing.

9. Add potentiator, if used, to tubes labeled 10-13. Add the potentiator in the amount specified in the manufacturer’s direction circular.

10. Incubate tubes 6 and 10-13 for 15-20 minutes at 36-38 °C or for the time specified by the manufacturer of the potentiator.

11. Wash the contents of tubes 6, 10-13 at least three times with isotonic saline, being careful to decant completely after each wash.

12. Add Anti-Human Globulin (polyspecific or Anti-IgG) to tubes 6, 10-13 in the amount specified by the manufacturer’s package insert. Mix the contents of the tubes thoroughly.

13. Centrifuge each tube. *Gently suspend each red blood cell button and examine macroscopically for agglutination. Grade and record results on the corQC Data Sheet.

*Suggested centrifugation time 15-30 seconds at 900-1000 x g or a time appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy suspension of antigen-negative red blood cells.

**Optional test reagents

**Reaction strength dependent on type of antiglobulin control cells used (weakly coated or strongly coated)

Legend: IS = immediate spin, SC = screening cell, IAT = indirect antiglobulin test, CCC = Coombs Control Cells or IgG-sensitized antiglobulin control red cells, AHG = Anti-Human Globulin containing anti-IgG

Limitations:

Falsely negative or falsely positive test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test reagents.

corQC reagents are intended for use in tests to determine the reactivity of routinely used blood bank reagents. Use of corQC reagents, or any other Quality Control Reagent, cannot provide assurance that false results will never occur during routine testing with any reagent evaluated.

corQC reagents are not designed for use in in vitro diagnostic tests. Their use should be limited to evaluation of routinely used blood bank reagents only.

The procedure provided in this circular describes daily QC testing of routine reagents where a source of red blood cells carrying the A, B and D antigens or a source of known weakly reactive antibodies are needed. The daily evaluation of other reagents, such as anti-A, other Blood Grouping Reagents (such as Anti-Fy, Anti-Jk, etc), Anti-C, C3, are described in their respective directions for use.

Reactions obtained in QC testing that are weaker than the average expected reactions described in this circular, are unacceptable. Factors contributing to unacceptable results include deterioration of the routine reagent under evaluation, suboptimal performance of test equipment such as washing devices and centrifuges, or poor testing technique of the operator. Less frequently, unacceptable results are an indication of failure of the QC reagents themselves. When the results of any QC test fail to meet expectations, the test should be repeated. Repeated failures necessitate a thorough investigation to identify the cause and to eliminate it.

Specific Performance Characteristics:

Prior to release, each lot of Immucor corQC is tested with licensed FDA reagents from two or more sources to insure that the product produces results within the ranges listed in this insert. The performance of this product is dependent upon adhering to the insert’s recommended methodology. For additional information or for technical support, contact Immucor at 855-IMMUCOR (446-8267).

Bibliography:


Insert code 381-6
Rev 06/17