UnityPoint Health Pekin
Department of Pathology
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Effective Date: 11/14/18
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TRM.31400

BLOOD BANK QUALITY CONTROL

corQC™ Test System

I. PRINCIPLE

UnityPoint Health-Pekin laboratory personnel will utilize this procedure to perform quality control testing. Results will be reviewed weekly by Blood Bank charge tech or designee.

II. CLINICAL SIGNIFICANCE

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.

Group AB, D+ red 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 anti-A, anti-B, anti-D and anti-C. It is used to test serum (reverse) grouping cells and antibody detection cells. Both reagents assist in monitoring the performance of potentiators and Anti-Human Globulin (anti-IgG component). CorQC™ Reagent Cells and corQC™ Reagent Antiserum should produce visible agglutination reactions with the reagents under test. No agglutination indicates reagent deterioration or technique failure.

III. REAGENT

A. CorQC™ Regent Cells: group AB, D+. The red cells have been prepared as a 2-4% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis and loss of antigenicity during the dating period. Chloramphenicol (0.25 mg/ml), neomycin sulfate (0.1 mg/ml) and gentamicin sulfate (0.05 mg/ml) are added as preservatives.

B. 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.

C. ABO cell grouping reagents
D. ABO serum grouping reagents
E. Anti-D and compatible ABO+Rh control
F. Antibody detection cells
G. Anti-Human Globulin (anti-IgG)
H. Cells sensitized with IgG
I. Potentiator (LISS)
J. Isotonic saline
K. Precautions:
    1. For in vitro diagnostic use.
    2. Store at 1-10° C when not in use. Do not freeze or expose to elevated temperatures. Do not use beyond expiration date. 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.
    3. 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.
    4. Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into the sink, flush with a large volume of water to prevent azide build-up.

IV. PROCEDURE:

A. Prior to performing daily QC testing, inspect all reagents under test (ABO reagents, Rh reagents, etc.) for evidence of contamination or deterioration i.e., marked turbidity of Blood Grouping Reagents or hemolysis of Reagent Red Blood Cells). Check the lot number and expiration date of each reagent and observations on the corQC™ data sheet.
B. Label one test tube for each reagent to be evaluated. Tubes can be labeled as follows:

Tube Number	Reagent
1	Anti-A
2	Anti-B
4	ABO+Rh Control
5	Anti-D
6	Anti-D
7	A_1 serum grouping cells
9	B serum grouping cells
10	Screening Cell I
11	Screening Cell II
12	Screening Cell III
13	Screening Cell I, II, or III (antiglobulin negative control)
14	Cells sensitized with IgG

8 Add 1 drop of each reagent to the appropriate tubes labeled in step B. In addition, add 1 drop of Anti-A or Anti-B to tube 13
9 Add 1 drop corQC™ Reagent Cells to tubes numbered 1-5.
10 Add 1 drop of reverse cells A or B to tube number 6.
11 Add 1 drop of corQc™ Antiserum to tubes numbered 7-12. Do not add corQc Antiserum to tube numbered 13.
12 Add 1 drop of saline to tube 14.
13 Centrifuge all tubes. Gently suspend each cell button and examine for agglutination. Record results on the corQc™ Data sheet.
14 Discard tubes 1-5, 7-9 and 14. Save tube 6 for further testing.
15 Add 2 drops LISS to tubes labeled 10-13.
16 Incubate tube 6 for 15 minutes and tubes 10-13 for 10 minutes at 36-38° C.
17 Wash the contents of tubes 6, 10-13 at least three times with saline, being careful to decant completely after each wash. (An automatic cell washer may be used).
18 Add Anti-Human Globulin (Anti-IgG) to tubes 6, 10-13. Mix the contents of the tubes thoroughly.
19 Centrifuge each tube. Gently suspend each cell button and examine macroscopically for agglutination. Grade and record results on the corQC™ data sheet.
20 Following centrifugation, all tests should be read immediately and results should be interpreted without delay. Delays may result in dissociation of antigen-antibody complexes leading to falsely negative, or at most, weakly positive reactions.
21 Add cells sensitized with IgG to any negative results. (Should be tube 6 and 13). Record reactions on the corQC™ data sheet. (UPPK BB-0522.01)

V. INTERPRETATION OF RESULTS

A. The expected results with corQC™ reagents are given in the chart below. Results obtained in actual testing should be compared to this chart.

B. Each day's results should also be compared to those obtained on previous days of testing. The strengths of reactions obtained on any day should be comparable to those indicated in this insert and should be consistent in strength from day to day when the same lots of serum of red cell reagents are being tested.

C. Test results that differ significantly from the expected, or results which vary greatly from day to day, are an indication that the reagents or techniques being evaluated in quality control testing are not satisfactory. A significant and verified decrease in the strength of reactions with any reagent should be evaluated since it can be an indication of reagent deterioration or equipment malfunction.

TUBE	REAGENT UNDER TEST	QC REAGENT	AVERAGE EXPECTED RESULTS	TEST CONFIRMS
1 2	Anti-A Anti-B	corQC™ Red Cells	2-4+ (IS)	Reactivity of ABO reagent
4 5	ABO+Rh Control Anti-D	corQC™ Red Cells	Neg (IS) 2-4 + (IS)	Performance of control reagent Reactivity of Anti-D
6	Anti-D	Reagent cells A^1, or B	Neg (IS, IAT)	Specificity of Anti-D
7 9	A_1 Cells B cells	cor QC™ Antiserum	2-4+ (IS) 2-4+ (IS)	Reactivity of reagent
10 11 12	SCI SCII SCIII	corQC™ Antiserum	1-3+ (IAT)	Reactivity of red cells
13	SCI, SCII, or SCIII	Anti-A or Anti-B	Neg (IAT)	Specificity of Anti-Human globulin
14	Cells sensitized with IgG	Saline	Neg (IS)	Performance of control reagent

LEGEND:
IS=immediate spin, **SC**=screening cell, **IAT**=indirect antiglobulin test

VI. LIMITATIONS:

A. Falsely negative or falsely positive test results can occur from bacterial or chemical contamination of test material, inadequate incubation time or

temperature, improper centrifugation, improper storage of material, or omission of test reagents.

B. 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. 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 indicator of failure of the QC reagents themselves. When the results of any QC test fails to meet expectations, the test should be repeated. Repeated failures necessitate a thorough investigation to identify the cause and to eliminate it.
C. No patient results/testing can be reported/interpreted if the QC results are not acceptable.

VII. REFERENCES

A. Immucor, Inc, Norcross GA., corQC™ Test System for Quality Control of Blood Bank Reagents, 381-6, Rev. 06/17.

POLICY CREATION :		***Date***
Author:	***Sharrol Brisbin, MT (ASCP)***	***02/01/1997***
Medical Director:	***Sheikh, MA, MD***	***02/01/1997***

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DATE	NAME	SIGNATURE
12-3-18	Kathryn O. Kramer MD	
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date
10/28/18	Remove Limitations	Jenny Turner	10/28/18
11/14/18	Add Limitations back	Jenny turner	11/14/18

Reviewed by

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date
Jennifer Turner	12-2-18				