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Quality Control of Blood Bank Reagents - Dearborn

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies and procedures relating to the routine quality control (QC) of manual reagents used in the Blood Bank.

II. CLINICAL SIGNIFICANCE:

A. A Quality Control (QC) Program is devised to confirm that reagents, equipment and methods in use fulfill their expected function on each day of use as well as confirm that personnel perform these procedures in approved reproducible fashion. Quality control of the reagents and diluents used for testing must be performed as described by manufacturers and/or various regulations. All technologists are not required to perform QC daily, but all should participate in the performance of QC on a regular basis. The expectations of QC testing must be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. A bottle of each lot in use for reagents used in testing patient ABO/Rh, antibody screens, and crossmatching are checked for proper reactivity daily. Non-routine antisera are checked each day of use or when a new vial is opened.

III. SCOPE:

A. The scope of this document includes the QC of reagents that are generally used in tube testing and manual gel methods.

B. The QC of the reagents used in the blood bank is organized by racks.

Rack	Contains reagents to perform the following procedures:
QCT	ABO/Rh testing by the tube method
	60-minute no-LISS indirect antiglobulin tests
	Direct antiglobulin tests
DQLIS	LISS indirect antiglobulin tests
QCG	Manual MTS Gel Testing

C. Refer to Transfusion Medicine Policies listed below for information on the quality control of reagents used

for testing on the Ortho Vision Analyzer, antigen testing, sickle cell testing, and fetal cell screening:

ORTHO VISION Analyzer QC

Antigen Typing

Fetal Cell Screening

Hemoglobin S Solubility Testing of Patients - Sickledex Method

Sickle Testing of Units

Kleihaeur Betke

IV. GENERAL POLICIES:

A. QC specimens should be tested in same manner as patient and donor samples, and by the same personnel who routinely perform testing of patient and donor samples.

B. The QC for a given test must be performed in parallel with or in advance of testing patient or donor samples.

C. The QC of all reagents in a rack must pass before the reagents may be used to test patient or donor samples.

D. The QC of the tube reagents used in ABO/Rh testing, and 60 minute -no-LISS testing is performed daily regardless of whether the reagent is used to test patient or donor samples on that day. All other tube reagents or methods not expected to be used each day for patient or unit testing are tested for quality control on each day of use.

E. QC testing for gel cards used for ABO/Rh typing, DAT and donor confirmatory typing is performed daily on the Ortho Vision, as described in Transfusion Medicine Policy, ORTHO VISION Analyzer QC If for any reason this QC testing is not performed on the Ortho Vision, then this QC testing must be performed by the manual gel card method as described in the procedure section of this document.

F. QC of the manual gel antibody screen is tested using a positive and a negative control against the Selectogen® and Surgiscreen® screening cells.

G. It is recommended by the manufacturer that panels should be tested periodically. The blood bank will test the primary panels (0.8% Ortho Panel A, B, C) with each delivery as each box is opened and put into use, and after the box has been in use for at least two weeks, if applicable. This QC is performed on the Ortho Vision as described in Transfusion Medicine Policy, ORTHO VISION Analyzer QC . Alternate panels used for additional confirmatory testing are subject to internal controls (inclusion of reactive and non-reactive cells) during routine use.

H. Typing sera and reagent cells must be checked for reactivity and specificity on each day of use, including a check against known positive and negative cells or anti-sera.

I. Each cell used in the antibody screen must be tested each day of use for reactivity of one antigen. These screening cells must test at least (1+) with appropriate anti-sera.

J. When testing the controls by the 60-minute no-LISS and LISS / AHG methods, IgG coated check cells must be used for all negative reactions. IgG coated checked cells are expected to have a positive reaction in any strength. If the check cells do not react as expected, the testing must be repeated.

K. When testing with complement in a DAT, complement coated check cells must be used. Complement coated check cells are expected to have a positive reaction, of any strength. If the check cells do not react as expected, the testing must be repeated.

L. Appearance of Reagents

1. Reagent red cells: Do not use the reagent red cells if discoloration or visual signs of hemolysis are present.
2. Diluents: Do not use the diluent if there is any evidence of discoloration, turbidity, or signs of contamination.
3. Blood Bank Saline: Saline should be clear, colorless, and have no signs of microbial growth or particulate matter. Do not use if hemolysis occurs during IAT testing, or if visual inspection detects any signs of microbial growth or a change in color or clarity.
4. Gel cards: Each well of the gel card should have a clear liquid layer on top of the opaque gel. Do not use gel cards if:
    a. the gel matrix is absent
    b. the liquid level in the microtube is at or below the top of the gel matrix
    c. the cards show signs of drying, discoloration, bubbles, crystals, or other artifacts
    d. foil seals appear damaged or opened.
5. Gel DAT Controls: Do not use the gel DAT controls if there are visible signs of hemolysis.
6. AlbaQ-Chek® Kit vials: Do not use if obviously discolored or hemolyzed. Slight discoloration of the supernatant is normal.

M. The appearance of all reagents must be inspected before they are used to test patient or donor samples, and the appearance must be satisfactory. The appearance is documented as satisfactory (S) or unsatisfactory (U) in the blood bank computer system or on corresponding downtime forms. Refer to Blood Bank CDM, *Documentation of the Manual QC Racks*.

N. Store all reagents according to manufacturer's recommendations to prevent environmentally induced alterations that could affect test performance.
    1. Tube Reagents
        a. Blood Bank Isotonic Saline must be stored at room temperature and must be in date.
        b. All reagents must be clear and in date. Store at 2°C to 8°C when not in use.
    2. Gel Reagents
        a. The MTS™ gel cards should be stored in an upright position at 2°C to 25°C, with the exception of the MTS™ Rh Phenotype and Antigen typing cards which are stored at 2°C to 8°C.
        b. The reagent red cells should be stored at 2°C to 8°C.
        c. The gel DAT controls should be stored at 2°C to 8°C.
        d. The diluents should be stored at 2°C to 8°C. When a new bottle is opened, the "open date" and the technologist's initials shall be written on the bottle. Use of the MTS diluent within 2 weeks of the date that it is opened minimizes the potential for contamination.

O. Rotation of Diluents
    1. The Blood Bank maintains two bottles of MTS Diluent 2 and MTS Diluent 2 PLUS™ with dispensers (with the same diluent lot number in each bottle).
    2. These bottles are rotated each day (so that one bottle is in use at room temperature and the other is stored at 2°C to 8°C). These two bottles are rotated at the same time as reagents used for Vision™ testing are rotated.

P. Expiration Dates
All reagents should be used within their indicated expiration date. Routine testing should be done with in-date reagents. Rare anti-sera may be used beyond their expiration date with Medical Director approval if appropriate positive and negative controls are run each day of use and result reactions are as expected.

V. DEFINITIONS:

A. QC: Quality Control

B. Daily: For quality control purposes,this is defined as the 24 hour period of testing from which QC was performed and documented on each calendar day. This QC is tested each day by technical staff, regardless of whether the reagent is used to test patient or donor samples on that day.

C. Each Day of Use: For quality control purposes, this is defined as the 24hr period of testing from which QC was performed and documented for a reagent not expected to be used daily to test patient or donor samples. The QC is only performed on days where reagent is used for testing.

D. AQ1: AlbaQ-Chek® Vial1 is QC sample known to be A negative(rr) containing Anti D

E. AQ2: AlbaQ-Chek®AlbaQ-Chek Vial 2 is QC sample known to be O positive(R1R1) containing anti-c.

F. AQ3: AlbaQ-Chek®AlbaQ-Chek Vial 3 is QC sample known to be B positive (R1r) containing Anti-A

G. AQ4-AlbaQ-Chek®AlbaQ-Chek Vial 4 is QC sample known to be A_2B positive with a negative screen.

H. 7BSA - Bovine Serum Albumin Control, 7%

I. CDM - Computer Documentation Manual; Computer Workflow

VI. REAGENTS:

A. Ortho Anti-A Bioclone

B. Ortho Anti-B Bioclone

C. Ortho Anti-D Bioclone

D. Immucor Gammaclone Anti-D or Series 4

E. Ortho 7%Bovine Serum Albumin

F. Immucor Gammaclone Rh Control

G. Ortho 3% Affirmagen cells (A1 and B Cells)

H. Ortho 3% Surgiscreen cells (Screening cells 1,2 & 3)

I. Ortho Coombs Control IgG Coated reagent red blood cells (CC)

J. Ortho Anti-Human Globulin IgG reagent (IgG)

K. Ortho Anti-Human Globulin IgG, C3d Polyspecific (Poly AHG)

L. Hemoscience C3 Control Cells

M. Ortho Antibody Enhancement Solution (OAES)

N. Alba Bioscience AlbaQ-Chek® QC Samples

O. Blood Bank Isotonic Saline (0.85 -0.9% NaCl)

P. MTS™ Diluent 2 Plus

Q. MTS™ Diluent 2

R. MTS™ Anti-IgG Gel cards

S. AlbaQ-Chek® Kit

T. MTS™A/B/D Monoclonal and Reverse Grouping Cards

U. MTS™ IgG Cards

V. MTS™A/B/D Forward Typing Cards

W. MTS™A/B Typing Cards

X. 0.8% AFFIRMAGEN® Reagent Red Blood Cells

Y. 0.8% Selectogen Screening Cells

Z. 0.8% Panel A ,B, C Cells

AA. Gel DAT Controls (Positive and Negative Controls)

VII. EQUIPMENT:

A. Table Top Centrifuge

B. Heat block, 37°C±1°C

C. Helmer cell washer

D. Agglutination Viewer

E. Ortho MTS Workstation

VIII. SUPPLIES:

A. Blood Bank Isotonic Saline

B. 12 x 75 mm tubes

C. Disposable Transfer Pipettes

D. Gauze

E. Calibrated pipette; either a manual pipette or the BioHit pipette.

F. Pipette tips

IX. EQUIPMENT / MAINTENANCE:

A. Determine the appropriate centrifugation time, as indicated on the Centrifuge Calibration Check sticker that is affixed to each serologic centrifuge. Refer to Transfusion Medicine Policy, *Functional Calibration of Serologic Centrifuges*.

B. Perform QC and Maintenance as defined in the Transfusion Medicine Policy, *Maintenance of the Ortho MTS Workstation*.

X. QUALITY CONTROL (QC):

A. The QC results and interpretations are documented in the blood bank computer system. Refer to Blood Bank CDM, *Documentation of the Manual QC Racks*. During computer downtimes, QC is documented on downtime forms.

B. Failing QC

1. The routine QC of reagents is interpreted as passing or failing based on expected results and visual inspections.
2. If the QC fails for any reason, the following apply:
   a. Test results of patient or donor samples may not be released unless / until QC passes.
   b. The QC will be repeated with the same reagents and controls.
   c. If the QC fails upon repeat then repeat with fresh opened controls.
   d. If the QC initially fails and fails upon repeat testing with the same lot number, then all vials of that lot number will be placed in quarantine. An internal variance form will be documented.
   e. Perform QC with a different lot number.
   f. Once placed in quarantine, reagents cannot be used to test patient or donor samples unless the Medical Director or supervisor indicates that the reagents may be used.

XI. PROCEDURE:

A. Performing QC of ABO & Rh Tube Reagents (Daily)

1. Evaluate the reagents in each rack for expiration dates.
2. Discard and replace with a new lot any reagents expiring on the current date or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of each reagent in the racks. All reagents should be free from turbidity. Red cell supernatants should be clear/colorless and free from marked hemolysis. See the policy; Appearance of Reagents for each type of reagent.
4. Label 10 test tubes consecutively.
5. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction
1	1 drop Anti-A	1 drop A1 cells	3+ or greater
2	1 drop Anti-A	1 drop B cells	negative
3	1 drop Anti-B	1 drop B cells	3+ or greater
4	1 drop Anti-B	1 drop A1 cells	negative
5	1 drop Ortho Bioclone Anti-D	1 drop Surgiscreen Cell # 1	2+ or greater
6	1 drop Ortho Bioclone Anti-D	1 drop Surgiscreen Cell # 3	negative
7	1 drop 7% BSA Control	1 drop Surgiscreen Cell # 2	negative
8	1 drop Gammaclone Anti-D	1 drop Surgiscreen Cell # 1	2+ or greater
9	1 drop Gammaclone Anti-D	1 drop Surgiscreen Cell # 3	negative
10	1 drop Gammaclone Control	1 drop Surgiscreen Cell # 2	negative

6. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
7. Read, grade, and record the reactions of each tube in the computer using QCT rack (or on the

attached downtime form, if applicable). Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reactions* and Blood Bank CDM, *Documentation of the Manual QC Racks*.

8. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction. If reactions do not conform to expected results, testing should be repeated. Refer to Quality Control; Failing QC above.
9. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the Interpretation section near the end of this document.

B. Performing the QC of the 60 Minute No-LISS Reagents (Daily)

1. Evaluate the reagents in each rack for expiration dates.
2. Discard and replace with a new lot any reagents expiring on the current date or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of each reagent in the racks. All reagents should be free from turbidity. Red cell supernatants should be clear/colorless and free from marked hemolysis. See the policy; Appearance of Reagents for each type of reagent.Evaluate the reagents in each rack for expiration dates.
4. Label 6 test tubes consecutively.
5. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction at the 37° C Phase	Expected Reaction at the AHG Phase
1	1 drop Surgiscreen cell # 1	3 drops of AlbaQ Vial 1	0 to 2+	1+, or 2+
2	1 drop Surgiscreen cell # 2	3 drops of AlbaQ Vial 1	0 to 2+	1+, or 2+
3	1 drop Surgiscreen cell # 3	3 drops of AlbaQ Vial 2	0 to 2+	1+, or 2+
4	1 drop Surgiscreen cell # 1	3 drops of AlbaQ Vial 4	negative	negative
5	1 drop Surgiscreen cell # 2	3 drops of AlbaQ Vial 4	negative	negative
6	1 drop Surgiscreen cell # 3	3 drops of AlbaQ Vial 4	negative	negative

Note: Do not add LISS reagent

6. Incubate the tubes at 37°C for 60 minutes.
7. Gently mix the contents of each tube and centrifuge according to the time calibrated for the

centrifuge.

8. Record the graded reactions of each tube, at each phase, in the blood bank computer using the QCT rack (or on the attached downtime form, if applicable). Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reactions* and Blood Bank CDM, *Documentation of the Manual QC Racks.*
9. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction. If reactions do not conform to expected results, testing should be repeated. Refer to policy; Failing QC above.
10. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the Interpretation section near the end of this document.

C. Performing the QC of the DAT Reagents (Daily)

1. Evaluate the reagents in each rack for expiration dates.
2. Discard and replace with a new lot any reagents expiring on the current date or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of each reagent in the racks. All reagents should be free from turbidity. Red cell supernatants should be clear/colorless and free from marked hemolysis. See the policy; Appearance of Reagents for each type of reagent.
4. Label 7 test tubes consecutively.
5. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction
1	2 drops polyspecific AHG	1 drop IgG coated check cells	2+ or greater
2	2 drops polyspecific AHG	1 drop complement coated check cells	positive (any strength)
3	2 drops polyspecific AHG	1 drop Surgiscreen Cell # 1	negative
4	2 drops Anti IgG AHG	1 drop IgG coated check cells	2+ or greater
5	2 drops Anti IgG AHG	1 drop complement coated check cells	negative
6	2 drops complement AHG	1 drop complement coated check cells	positive (any strength)
7	2 drops complement AHG	1 drop IgG coated check cells	negative

6. Incubate the contents of each tube for 5 minutes at room temperature.
7. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
8. Read, grade, and record the reactions of each tube, at each phase, in the computer using the QCT rack (or on the attached downtime form, if applicable). Refer to Transfusion Medicine Policy,

Reading, Grading and Recording Test Reactions and Blood Bank CDM, *Documentation of the Manual QC Racks.*

9. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
10. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the Interpretation section near the end of this document.

D. Performing the QC of the LIS Method/Reagents (Each Day of Use)

1. Evaluate the reagents in each rack for expiration dates.
2. Discard and replace with a new lot any reagents expiring on the current date or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of each reagent in the racks. All reagents should be free from turbidity. Red cell supernatants should be clear/colorless and free from marked hemolysis. See the policy; Appearance of Reagents for each type of reagent.
4. Label 7 test tubes consecutively.
5. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	# Drops of Reagent	Expected Reaction at the 37°C Phase	Expected Reaction at the AHG Phase
1	1 drop Surgiscreen Cell # 1	2 drops AlbaQ Vial 1	2 drops LISS	0 to 2+	1+,or 2+
2	1 drop Surgiscreen Cell # 2	2 drops AlbaQ Vial1	2 drops LISS	0 to 2+	1+,or 2+
3	1 drop Surgiscreen Cell # 3	2 drops AlbaQ Vial 2	2 drops LISS	0 to 2+	1+,or 2+
4	1 drop Surgiscreen Cell # 1	2 drops AlbaQ Vial 4	2 drops LISS	negative	negative
5	1 drop Surgiscreen Cell # 2	2 drops AlbaQ Vial 4	2 drops LISS	negative	negative
6	1 drop Surgiscreen Cell # 3	2 drops AlbaQ Vial 4	2 drops LISS	negative	negative
7	2 drops Anti-IgG AHG	1 drop IgG coated check cells	NA	NA	2+ or greater

6. Proceed as follows:
   a. Tubes# 1 – 6 : After adding 2 drops of LISS, incubate the tubes at 37°C for 15 minutes,

complete the LISS antibody screen, and control with IgG coated check cells.
Note: Read and record results for 37°C, AHG, and check cells.

b. Tube #7 : Gently mix the contents of the tube, and centrifuge according to the time calibrated for the centrifuge.

7. Record the graded reactions of each tube, at each phase, in the computer using the DQLIS rack (or on the attached downtime form, if applicable). Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reactions* and Blood Bank CDM, *Documentation of the Manual QC Racks.*
8. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
9. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the Interpretation section near the end of this document.

E. Performing QC of the Manual Gel Reagents (Daily)

1. Evaluate the reagents in each rack for expiration dates.
2. Discard and replace with a new lot any reagents expiring on the current date or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of the Selectogen® cells, Surgiscreen® cells, the IgG gel cards, and the positive and negative gel controls; see the policy Appearance of Reagents.
4. Prepare 0.8% cell suspensions for each of the 3% Surgiscreen® cells
   a. Label three 12x75 test tubes SC1,SC2, SC3.
   b. Dispense 100 µL of a 3% reagent red cell into a appropriately labeled tube, using either a manual pipette or an electronic pipette.
   c. Add a few drops of MTS Diluent 2™ into each tube to give sufficient liquid to decant.
   d. Centrifuge the tubes for 60 seconds to pack the RBCs.
   e. Invert the test tubes to completely remove the supernatant.
   f. Dispense 200 µL of MTS Diluent 2™ into the test tube of packed RBCs.
   g. Mix the test tube to resuspend the 0.8% red cell suspension.
   Note: If the diluted reagent cell suspension is being retained following the initial testing, it must be labeled with a *Selected Cell Sticker.*
   Refer to Transfusion Medicine Policy, Making a Test Red Cell Suspension
5. Label 10 wells of IgG gel cards, for example:

Well 1	Well 2	Well 3	Well 4		
AQ1 vs. Scr1	AQ3 vs Scr1	AQ1 vs Scr 2	AQ3 vs Scr 2		

Well 5	Well 6	Well 7	Well 8	Well 9	Well 10
AQ1 vs. SC1	AQ3 vs SC1	AQ1 vs SC2	AQ3 vs SC2	AQ2 vs SC3	AQ3 vs SC3

6. Remove the foil from the applicable wells of the gel card.
7. Add 50 µl of screen cells, and then add 25µl of control as specified in the table

Well #	Volume Screen Cells	Volume Control	Expected Reaction
1	50 µl Scr1 (0.8% Selectogen Cell 1)	25 µl AlbaQ Vial1	3+ or 4+
2	50 µl Scr1 (0.8% Selectogen Cell 1)	25 µl AlbaQ Vial 3	0
3	50 µl Scr2 (0.8% Selectogen Cell 2)	25 µl AlbaQ Vial 1	3+ or 4+
4	50 µl Scr2 (0.8% Selectogen Cell 2)	25 µl AlbaQ Vial 3	0
5	50 µl SC1 (converted from 3% Surgiscreen Cell 1)	25 µl AlbaQ Vial 1	3+ or 4+
6	50 µl SC1 (converted from 3% Surgiscreen Cell 1)	25 µl AlbaQ Vial 3	0
7	50 µl SC2 (converted from 3% Surgiscreen Cell 2)	25 µl AlbaQ Vial 1	3+ or 4+
8	50 µl SC2 (converted from 3% Surgiscreen Cell 2)	25 µl AlbaQ Vial 3	0
9	50 µl SC2 (converted from 3% Surgiscreen Cell 3)	25 µl AlbaQ Vial 2	3+ or 4+
10	50 µl SC2 (converted from 3% Surgiscreen Cell 3)	25 µl AlbaQ Vial 3	0

8. Incubate the gel card at 37°C ± 2°C for 15 minutes, not to exceed 30 minutes.
9. Centrifuge the gel card at 1032 ± 10 rpm for 10 minutes.
10. Read both front and back of the card for agglutination and grade reactions.Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reaction*.
11. Record the reactions in the blood bank computer using the QCG Rack (or on the attached downtime form, if applicable). Refer to Blood Bank CDM, *Documentation of the Manual QC Racks*.
12. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction listed on the table above.
13. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC as Pass or Fail; refer to the Interpretation section near the end of this document.

F. Performing the Gel DAT QC (As Needed)
Note: This QC is performed as needed if it is not performed on the Ortho Vision® on the current date.

1. Evaluate the appearance of the positive and negative gel DAT controls, the IgG gel cards, and the MTS Diluent 2™; see the policy Appearance of Reagents.
2. Label two 12 x 75 mm test tubes; e.g., POS DAT CONTROL, and NEG DAT CONTROL.
    a. In each of the correspondingly labeled tubes, prepare a 0.8% cell suspension for each gel DAT control using the MTS Diluent 2™. Refer to Transfusion Medicine Policy, Making a Test Red

Cell Suspension

b. Label 2 wells of an IgG gel card, for example:

Well 1	Well 2				
Pos Gel DAT	Neg Gel DAT				

c. Remove the foil from the applicable wells of the gel card.

d. Add 50 µl of each gel DAT control to the corresponding IgG card well, as described in the table below:

Well #	Volume of Gel DAT Control	Expected Reaction
1	50µL Positive Gel DAT Control	Any positive reaction
2	50µL Negative Gel DAT Control	0

e. Centrifuge the gel card at 1032 ± 10 rpm for 10 minutes.

f. Read both front and back of the card for agglutination and grade reactions.Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reaction.*

g. Record the reactions in the blood bank computer (or on the downtime form, if applicable). Refer to Blood Bank CDM, *Documentation of the Manual QC Racks.*

h. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.

i. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the Interpretation section near the end of this document.

G. Performing the Manual Gel ABO/Rh QC (As Needed)
Note: This QC is performed as needed if it is not performed on the Ortho Vision® on the current date.

1. Perform forward and reverse ABO/Rh testing of Alba Q vials 1 and 3 using the manual gel procedure described in Transfusion Medicine Policy, Determining The ABO and RhD Of Patients Who Are At Least Four Months Old
2. Read both front and back of the card for agglutination and grade reactions.Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reaction.*
3. Record the reactions in the blood bank computer (or on the downtime form, if applicable). Refer to Blood Bank CDM, *Documentation of the Manual QC Racks.*
4. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.

AlbaQ Sample	Test Performed	Expected Result
AlbaQ Vial 1	Forward and Reverse ABO/Rh	A Negative
AlbaQ Vial 3	Forward and Reverse ABO/Rh	B Positive

5. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the Interpretation section near the end of this document.

H. Performing the Antibody Panel QC (As Needed)

Note: This QC is performed as needed if it is not performed on the Ortho Vision®

1. Evaluate the appearance of the AlbaQ Controls and Panel Cells. Refer to policy; Appearance of Reagents.
2. Label 2 IgG gel cards for each panel to be tested. For Example,

Well 1	Well 2	Well 3	Well 4	Well 5	Well 6	Well 7	Well 8	Well 9	Well 10	Well 11
Panel A cell 1	Panel A cell 2	Panel A cell 3	Panel A cell 4	Panel A cell 5	Panel A cell 6	Panel A cell 7	Panel A cell 8	Panel A cell 9	Panel A cell 10	Panel A cell 11

3. Remove the foil from the applicable wells of the gel card.
4. Add 50 µL of each panel cell to the corresponding IgG card well.
5. Add 25 µL of positive gel control to each well.

Panel	Positive Gel Control	Expected Reaction	Interpretation
A	AlbaQ Vial 1	3+/4+ (D Pos cells)	Anti-D
B	AlbaQ Vial 2	3+/4+ (c pos cells)	Anti-c
C	AlbaQ Vial 1	3+/4+ (D pos cells)	Anti-D

6. Centrifuge the gel card at 1032 ± 10 rpm for 10 minutes.
7. Read both front and back of the card for agglutination and grade reactions.Refer to Transfusion Medicine Policy, *Reading, Grading and Recording Test Reaction.*
8. Record the reactions on the appropriate panel antigram sheet for the lot# being tested.
9. Evaluate the performance of the reagents by comparing the observed reaction with the expected reactions such that the positive antigen cells reacted positively and the negative antigen cells reacted negatively.

XII. INTERPRETATION:

A. Appearance of Reagents: Refer to the policy; Appearance of Reagents in evaluating whether the appearance is satisfactory or unsatisfactory.

B. Performance of Reagents: The performance of the reagent is evaluated by comparing the observed reactions with the expected reactions. The expected reactions are listed in the Procedure for each reagent.

1. The performance is considered satisfactory if the observed reactions match the expected reactions.
2. The performance is considered unsatisfactory if the observed reactions do not match the expected reactions
3. Reagents must not be used for patient testing if either the appearance or the Quality Control results of the reagents are not acceptable.

Appearance of Reagents	Performance of Reagents	QC Interpretation
Satisfactory	Satisfactory	PASS
Satisfactory	Unsatisfactory	FAIL

Unsatisfactory	Satisfactory	FAIL
Unsatisfactory	Unsatisfactory	FAIL

XIII. SPECIAL NOTES:

A. QC is documented in designated racks defined and stored in Blood Bank computer system. The system automatically begins a 24 hour clock from the time rack is first opened on the calendar day.

B. Generally, QC of the manual gel reagents (QCG rack) is performed by the midnight technical staff.

C. Generally, QC of the manual tube reagents (QCT rack) is performed by the dayshift staff.

D. Special anti-sera should be monitored with a positive (Heterozygous when appropriate) and negative control cell at the time the test is performed and recorded on the QC rack corresponding to the method used in the Bloodbank system or during a downtime, on the Antigen Typing Downtime Worksheet. These controls are run on the day of use. For acceptable QC, the controls for that anti-sera are considered effective for the remainder of the calendar day. Refer to Transfusion Medicine Policy, *Antigen Testing.*

E. Variations in red blood cell concentration can markedly affect the sensitivity of test results. If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in antigen/antibody ratio. In addition, red blood cells may fail to completely migrate to the bottom of the microtube and could cause a false positive interpretation. When red blood cells are too low in concentration, they become difficult to visualize and, in extreme cases, a weak positive can fail to be detected.

F. False positive or false negative test results can occur from bacterial contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples.

G. Anomalous results may be caused by fresh serum, fibrin or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube. Anomalous results, such as a line of red blood cells at the top of the gel, may be observed with serum samples and can be minimized with the use of EDTA plasma.

H. All QC records are kept indefinitely in the Laboratory Information System or for a minimum of 5 years on downtime.

XIV. REFERENCES:

1. College of American Pathologists TRM 31400, Antisera / Reagent Red Cell QC, 06/04/2020
2. American Association of Blood Banks. Technical Manual, current edition.
3. American Association of Blood Banks. Standards for Blood Banks and Transfusion Services, current edition.
4. Ortho Anti-Human Globulin Bio-Clone, Qualitative Procedure the Detection of Cell Bound Blood Group Antibody and/or Components of Complement, revised 01/2013
5. Ortho™ reagent Instructions for Use.
6. Immucor® reagent Instructions for Use.
7. AlbaQ-Chek® Instructions for Use.
8. Micro Typing Systems Instructions For Use – Update Packet, Pub. No. J3308EN, 06/09/2010.
9. ID-Micro Typing System® Implementation Guide 6902200

Attachments

Antigen Typing Downtime Worksheet.pdf
Downtime QC Form Manual Gel QCG Rack.pdf
Downtime QC Form Manual Tube DQLIS Rack.pdf
Downtime QC Form Manual Tube QCT Rack.pdf

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	11/15/2021
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	11/15/2021
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	11/15/2021
	Kimberly Geck: Dir, Lab Operations B	11/15/2021
	Kelly Sartor: Supv, Laboratory	11/15/2021
	Kelly Sartor: Supv, Laboratory	11/15/2021

Applicability

Dearborn

Beaumont HEALTH

Beaumont Laboratory, Dearborn

Antigen Typing Downtime Worksheet

Date and Tech	Patient/ Donor Number	Antigen	Method (Tube or Gel/IgG or Gel/Rh)	Anti-sera or Rh Gel Card (Mfg / lot# / exp)	* Controls															Donor Result					QC A/P (S/U)	Interpret Unit		Recorded in Soft (Tech)	QC Review of Negative Units (Date / Tech)
					Panel (Mfg /lot# / exp)	Pos Cell #	Neg Cell #	Pos Ctrl Result					Neg Ctrl Result														Antigen	(Pos or Neg)		
								IS	RT	AG	CC	GEL	IS	RT	AG	CC	GEL													

* Results are documented only for phases tested.

Applicable SOPs: *Antigen Typing and Quality Control of Blood Bank Reagent Procedures.*

Beaumont HEALTH
Beaumont Laboratory, Dearborn

Downtime Form: Manual Gel Quality Control (QCG)

Antibody Screening (Performed daily)

Date:	Technologist:	
Reagent	Lot # & Expiration Date,	Lot # & Expiration
Positive control AlbaQ1		
Positive control AlbaQ2		
Negative control AlbaQ3		
MTS™ Anti-IgG Gel Card		
2-Cell Selectogen® 0.8% Screen Cells:		
3-Cell Surgiscreen® 3.0% Screen Cells:		
MTS™ Diluent 2		

Reagents		Control	Observed Results	Expected Results	Appearance/ Performance (S)atisfactory or (U)nsatisfactory	QC Pass/Fail
0.8% SCI	MTS™ Anti-IgG Gel Card	AlbaQ1		3+/4+		
		AlbaQ3		0		
0.8% SCII		AlbaQ1		3+/4+		
		AlbaQ3		0		
3.0% SCI DILUTED	MTS™ Anti-IgG Gel Card	AlbaQ1		3+/4+		
		AlbaQ3		0		
3.0% SCII DILUTED		AlbaQ1		3+/4+		
		AlbaQ3		0		
3.0% SCIII DILUTED		AlbaQ2		3+/4+		
		AlbaQ3		0		

Data Recouped by: _____

Data Reviewed by/ Date: _____

Applicable SOPs: *Quality Control of the Blood Bank Reagents.*

Downtime Form: Manual Gel Quality Control (QCG)

DAT Gel Testing* (performed only as required)

Date:		Technologist:		
Reagent		Lot #, Expiration Date	Lot #, Expiration Date	
Positive Gel DAT Control				
Negative Gel DAT Control				
MTS™ Anti-IgG Gel Card				
MTS Diluent 2				
Control	Observed Results	Expected Results	Appearance/ Performance (S)atisfactory or (U)nsatisfactory	QC Pass/Fail
DAT Pos		Any Positive Reaction		
DAT Neg		0		

Data Recouped by/Date: _____

QC Reviewed by/Date: _____

Applicable SOPs: *Quality Control of the Blood Bank Reagents.*

Downtime Form: Manual Gel Quality Control (QCG)

ABORh Testing* (performed only as required)

Date:	Technologist:	
Reagent	Lot #, Expiration Date	Lot #, Expiration Date
AlbaQ1 Control		
AlbaQ3 Control		
MTS MTS™ Diluent 2 Plus		
MTS™ ABD/Reverse Gel Card		
0.8% Affirmagen Cells		

Reagents		Control	Observed Results	Expected Results	Appearance/ Performance (S)atisfactory or (U)nsatisfactory	QC Pass/Fail
Anti A	MTS™ ABD/Reverse Gel Card	AlbaQ1		3+/4+		
		AlbaQ3		0		
Anti B		AlbaQ1		0		
		AlbaQ3		3+/4+		
Anti D		AlbaQ1		0		
		AlbaQ3		3+/4+		
Control		AlbaQ1		0		
		AlbaQ3		0		
A1 Cells		AlbaQ1		0		
		AlbaQ3		3+/4+		
B Cells		AlbaQ1		3+/4+		
		AlbaQ3		0		

Data Recouped by/Date: _____

QC Reviewed by/Date: _____

Applicable SOPs: *Quality Control of the Blood Bank Reagents.*

Beaumont HEALTH

Beaumont Laboratory, Dearborn

Downtime Form: Manual Tube DQLIS Rack

LISS/AHG Method

Date:					Technologist:				
Reagent					Manufacturer, Lot #, Expiration Date				
Positive tube control (AlbaQ 1)									
Positive tube control (AlbaQ 2)									
Negative tube control (AlbaQ 4)									
3-Cell Surgiscreen ® Screen Cells									
Anti-IgG									
Check Cells									
LISS									
Reagent	Control	Observed Results			Expected Results			A/P	QC Int.
		37	AHG	CC*	37	AHG	CC*		
Pos tube control AlbaQ 1	SCR I				0 to 2+	1+ or 2+	2+ or greater		
Pos tube control AlbaQ 1	SCR II				0 to 2+	1+ or 2+	2+ or greater		
Pos tube control AlbaQ 2	SCR III				0 to 2+	1+ or 2+	2+ or greater		
Neg tube control AlbaQ 4	SCR I				0	0	2+ or greater		
Neg tube control AlbaQ 4	SCR II				0	0	2+ or greater		
Neg tube control AlbaQ 4	SCR III				0	0	2+ or greater		
Anti-IgG vs. Check Cells (immediate-spin)					2+ or greater				
LISS (visual inspection)					Satisfactory				
Technologist									

* Check cells must be tested if the graded reaction at the AHG phase is weaker than 2+. The graded reaction after the addition of the check cells must be at least 2+. If these requirements are not met, then the test is not valid and must be repeated.

Data Recouped by/Date: _____ Reviewed By/Date: _____

Beaumont HEALTH

Beaumont Laboratory
Dearborn

Downtime Form: Manual Tube Reagent QC (QCT Rack)

ABO/Rh Tube Testing

Date:		Technologist:			
Reagent	Mfg., Lot #, Expiration Date				
Anti-A					
Anti-B					
Anti-D Ortho BioClone					
6-8% Bovine Albumin Control					
Anti-D GammaClone					
GammaClone Control					
A1 Reverse Cell					
B Reverse Cell					
Surgiscreen® Screen Cells					

Reagent	Control	Observed Results	Expected Results	Appearance/ Performance S/U	QC Interpretation P/F
Anti-A	A1cells		3+ or 4+		
Anti-A	B cells		0		
Anti-B	B cells		3+ or 4+		
Anti-B	A1 cells		0		
Anti-D Ortho BioClone	SCR I		2+ or 3+ or 4+		
Anti-D Ortho BioClone	SCR III		0		
6-8% Bovine Albumin Control	SCR II		0		
Anti-D GammaClone	SCR I		2+ or 3+ or 4+		
Anti-D GammaClone	SCR III		0		
GammaClone Control	SCR II		0		

Data Recouped by/Date: _____ Reviewed By/Date: _____

60 Minute-No LISS Method

Applicable SOP: *Quality Control of Blood Bank Reagents*.

Date:					Technologist:				
Reagent					Manufacturer, Lot #, Expiration Date			Manufacturer, Lot #, Expiration Date	
Positive tube control (AlbaQ 1)									
Positive tube control (AlbaQ 2)									
Negative control (AlbaQ 4)									
3-Cell Surgiscreen ® Screen Cells									
Anti-IgG									
Check Cells									
Reagent	Control	Observed Results			Expected Results			Appearance /Performance S/U	QC Interpretation P/F
		37	AHG	CC*	37	AHG	CC*		
SCR I	Pos tube control AlbaQ 1				0 to 2+	1+ or 2+	2+ or greater		
SCR II	Pos tube control AlbaQ 1				0 to 2+	1+ or 2+	2+ or greater		
SCR III	Pos tube control AlbaQ 2				0 to 2+	1+ or 2+	2+ or greater		
SCR I	Neg tube control AlbaQ 4				0	0	2+ or greater		
SCR II	Neg tube control AlbaQ 4				0	0	2+ or greater		
SCR III	Neg tube control AlbaQ 4				0	0	2+ or greater		
Technologist									

Data Recouped by/Date: _____ Reviewed By/Date: _____

Beaumont HEALTH

Beaumont Laboratory
Dearborn

Downtime Form: Manual Tube Reagent QC (QCT Rack)

Direct Antiglobulin (DAT) Testing

Date:		Technologist:			
Reagent	Mfg., Lot #, Exp. Date				
Polyspecific AHG					
Anti-IgG					
Anti-C3b,d					
IgG Check Cells					
Complement Check Cells					
Surgiscreen® Screen Cells					
Reagent	Control	Observed Results	Expected Results	A/P	QC Int.
Polyspecific AHG	IgG Check Cells		2+ or greater		
Polyspecific AHG	Complement Check Cells		Positive (any strength)		
Polyspecific AHG	SCI		0		
Anti-IgG	IgG Check Cells		2+ or greater		
Anti-IgG	Complement Check Cells		0		
Anti-C3b,d	Complement Check Cells		Positive (any strength)		
Anti-C3b,d	IgG Check Cells		0		

Data Recouped by/Date: _____ Reviewed By/Date: _____

Applicable SOP: *Quality Control of Blood Bank Reagents.*