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Quality Control of Blood Bank Reagents - Royal Oak

Document Type: Procedure

I. PURPOSE:

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

II. SCOPE:

A. The QC of the reagents used in the Blood Bank is organized by racks. The scope of this document includes the QC of reagents that are generally used in tube testing methods and in the manual gel system, which are organized in the following racks:

Rack:	Contains reagents to perform the following procedures:
RQ1 and RQ2	ABO/Rh testing by the tube method
RQ60M	60-minute no-LISS indirect antiglobulin tests
RQLIS	LISS indirect antiglobulin tests
RQDAT	Direct antiglobulin tests
RQSCD, RQSCA, RQSCM	Manual gel antibody screens
GDAT	Manual gel direct antiglobulin tests
SALIN	Saline used for routine Blood Bank testing and QC.

B. Refer to the policies below for information related to QC of reagents for the ORTHO VISION™, antigen typing, fetal cell screening, pipettes used in the manual gel system, and manual gel system equipment.

1. Transfusion Medicine policy, ORTHO VISION Anaylzer QC

2. Transfusion Medicine policy, *Antigen Typing*
3. Transfusion Medicine policy, *Fetal Cell Screening Using the FMH Rapid Screen Kit*
4. Transfusion Medicine policy, *Pipette Calibration Verification*
5. Transfusion Medicine policy, *Quality Control of the Manual Gel System: Incubators, Centrifuges, and Diluent Dispensers*.

III. PRINCIPLE:

A. QC testing is performed to verify the proper functioning of materials, equipment, and methods during operation. QC specimens should be tested in the same manner as patient and donor samples, and by the same personnel who routinely perform testing of patient and donor samples.

B. QC of the reagents and diluents used for testing in the manual gel system must be performed as described by various regulations and by the manufacturer of the manual gel system. For example, these regulations require that each cell used for antibody detection must be checked each day of use. 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 antisera. Ortho Clinical Diagnostics (OCD) recommends testing each gel card lot on each day of use with known antigen positive and antigen negative red blood cells (RBCs). These requirements are satisfied as described throughout this document.

C. Saline supplies within the Blood Bank must also undergo quality control daily. This quality control is performed in the ID-Micro Typing System (manual gel system).

D. 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.

IV. DEFINITIONS:

A. **Each day**: The QC is tested each day, regardless of whether the reagent is used to test patient or donor samples on that day. QC is defined each day for reagents that are expected to be used each day or most days.

B. **Each day of use**: The QC is tested each day that the reagent is used to test patient or donor samples. QC is defined each day of use for reagents that are not expected to be used each day.

C. **Indirect antiglobulin test (IAT)**: Test that demonstrates in-vitro reactions between RBCs and antibodies. For QC within this document, both controls and reagent RBCs are pipetted into wells of a MTS™ Anti-IgG gel card, incubated at 37°C ± 2°C, and then centrifuged to determine the presence of agglutination.

D. **"Boxed" saline**: Blood Bank saline that is stored within the original product packaging (cardboard cube). This saline source is routinely used for Blood Bank's automated instruments. Saline expires 1 month after opening the cube.

E. **"Bottled" saline**: Blood Bank saline that is stored in clear saline bottles located throughout the Blood Bank. The saline cube used to fill the saline bottles (the "parent" cube) will undergo QC

along with the bottles. Saline expires 1 month after the "parent" cube is opened.

V. POLICIES:

The QC for a given test must be performed in advance of testing patient or donor samples. The QC for all reagents in a rack must pass before the reagents in the rack may be used to test patient or donor samples.

A. Storage of Reagents

1. MTS™ gel cards should be stored in an upright position at 2°C to 25°C, with the exception of the MTS™ Monoclonal Rh Antigen typing cards and MTS™ Rh Phenotype cards which are stored at 1°C to 8°C.
2. The reagent red cells should be stored at 2°C to 8°C.
3. The gel DAT control should be stored at 2°C to 8°C.
4. 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 1 month of the date that it is opened minimizes the potential for contamination.
5. Blood Bank saline should be stored at room temperature (15°C - 30°C).
6. Reagents in the RQ60M, RQLIS, and RQDAT racks should be stored at 2°C to 8°C.
7. Reagents in the RQ1 and RQ2 racks that are in-use are kept at room temperature, additional vials of reagent are stored at 2°C to 8°C.

B. Appearance of Reagents

1. 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 in the Blood Bank computer (or on the applicable downtime form) as satisfactory (S) or unsatisfactory (U) as described in the Blood Bank CDMs, *Documentation of the RQ1 and RQ2 Racks* and *Documentation of the RQDAT, RQSCM, RQSCD, RQSCA, GDAT and SALIN Racks*.
2. Reagents should not be used beyond expiration date. See the policy *Reagent Expiration Date*, below.
    a. Diluents: Do not use the diluent if there is any evidence of discoloration, turbidity, or signs of contamination.
    b. 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:
        i. The gel matrix is absent.
        ii. The liquid level in the microtube is at or below the top of the gel matrix.
        iii. The cards show signs of drying, discoloration, bubbles, crystals, or other artifacts.
        iv. Foil seals appear damaged or opened.
    c. Reagent red cells: Do not use the reagent red cells if there is discoloration, visible

signs of hemolysis, or leaking vials.

d. AlbaQ-Chek® Kit vials: Do not use if obviously discolored or hemolyzed. Slight discoloration of the supernatant is normal.

e. Anti-sera, AHG reagents, LISS, Rh controls: Do not use if there is marked turbidity or leaking vials.

f. Gel DAT controls: Do not use the gel DAT controls if there are visible signs of hemolysis.

g. 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.

C. Check Cells

1. When testing the controls by the 60-minute no-LISS and LISS / AHG methods, check cells must be used if the reaction of the control at the AHG phase is negative.
2. The check cells are expected to react positive at any strength. If the check cells do not react as expected, the testing must be repeated.

D. Rotation of Diluents

1. The Blood Bank maintains two bottles of MTS Diluent 2™ with dispensers (with the same diluent lot number in each bottle). These bottles are rotated every 24 hours on the midnight shift (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 the diluents used for testing on the ORTHO VISION™.
2. One bottle of MTS Diluent 2 PLUS™ with a dispenser is returned to 2°C to 8°C when not in use.

E. Panel QC Testing

1. It is recommended by the manufacturer that panels should be tested periodically. The Blood Bank will test the primary panel (0.8% Ortho® Panel A) as each box is opened and put into use, and after the box has been in use for at least two weeks, if applicable. Alternate panels used for additional confirmatory testing are subject to internal controls (inclusion of reactive and non-reactive cells) during routine use.

F. Reagent QC Testing and Frequency

1. Each shift, QC of the manual gel antibody screen is tested using a positive and a negative control against the SELECTOGEN® screening cells. These controls are referred to as the positive gel control (AlbaQ vial 1) and the negative control (AlbaQ vial 4). This QC is documented by each shift (days, afternoons, and midnights) using the RQSCD, RQSCA, and RQSCM racks.
2. Each day, QC of the following racks is performed: RQ1, RQ2, RQ60M and RQDAT.

3. QC for the RQLIS rack is performed each day of use.
4. Each day, the positive and negative gel DAT controls are tested using the MTS™ Anti-IgG gel cards. This QC is documented by the midnight shift using the GDAT rack. Refer to Transfusion Medicine policy, Preparation of Positive and Negative Gel DAT QC Samples to create the gel DAT controls.
5. Each day, QC must be performed on the Blood Bank's saline supply. The saline should be visually inspected and tested as a negative control in the IAT. QC will be performed on both "boxed" and "bottled" saline against the SELECTOGEN® screening cells. This QC is documented by the midnight shift using the SALIN rack.
    a. Since there are multiple bottles of saline throughout the Blood Bank, the specific bottle tested for the "bottled" saline QC will rotate based on the day of the week, as described in the *Procedure* section of this document.
    b. To differentiate between possible overlaps of lot numbers for "bottled" and "boxed" saline, "boxed" saline will have the printed lot number on the packaging followed by an "X". The lot number for the "bottled" saline will be the lot number printed on the package alone.
6. During computer downtimes, QC of these racks will be documented on *Downtime Form: Racks RQSCD, RQSCA, RQSCM, GDAT, and SALIN*, *Downtime Form: Racks RQ1, RQ2 and RQ3, Downtime Form: Racks RQ60M and RQLIS*, and *Downtime Form: RQDAT Rack*.
7. Note that the RQSCD, RQSCA, and RQSCM racks are selected when performing a manual gel antibody screen. The GDAT rack is selected when performing a gel DAT or a manual gel crossmatch.
8. Each day, QC testing is performed using the AlbaQ-Chek® Kit vials and the gel cards used for ABO/Rh typing. This QC testing is performed 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. This QC is documented on the *Downtime Form: QC of Manual Gel ABO/Rh Testing*.
9. Each time an Ortho® 0.8% Panel A is opened, the panel is tested using the positive control against the entire panel. This QC is documented by the technologist that opens a new box of Panel A on the Panel A Antigram located on a clipboard at the Problems bench and on the *Panel A Quality Control* sticker that is attached to the box. This QC is also performed and after the box has been in use for at least two weeks, if applicable.

G. Reagent Expiration Date

1. All reagents should be used within their indicated expiration date. Routine testing should be done with in-date reagents.
2. Rare antisera may be used beyond their expiration date with Medical Director approval, if appropriate positive and negative controls are run each day of use and react as expected.
3. Documentation of the Medical Director approval as well as results should be documented as an internal unit comment or patient comment, depending on how the antisera is used.

H. Failing QC

1. As described in the *Interpretation* section of this document, the routine QC of reagents is interpreted as passing or failing based on the expected results and the visual inspection. If QC fails for any reason, the following apply:
    a. A variance will be submitted.
    b. Test results of patient or donor samples may not be released unless / until QC passes.
    c. The QC will be repeated with the same lot number.
    d. The QC will be repeated with newly opened controls.
    e. If QC fails upon repeat with the same lot number, then the QC will be tested with a different lot number of reagent, if possible.
    f. 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. Perform QC with a different lot number.
    g. Once placed in quarantine, reagents cannot be used to test patient or donor samples unless the Medical Director or manager / supervisor indicates that the reagents may be used.
    h. Consult with Manager and Medical Director for the appropriate course of action for specimens already processed or released during the failure period.
    i. Repeat patient testing as necessary and correct results as warranted in the LIS. Notify appropriate clinical staff of any corrected reports.
2. Failing QC of Panel A:
    a. An electronic variance will be submitted.
    b. Test results of patient or donor samples may not be released unless / until QC passes.
    c. The QC will be repeated with a new vial of the positive gel control.
    d. The QC will be repeated with a new box of Panel A.
    e. If the QC fails upon repeat with the same lot number, then the QC will be tested with a different lot number of Panel A reagent, if possible.
    f. 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. Perform QC with a different lot number.
    g. If the QC fails for each box and lot of Panel A, Panel C can be used as our primary panel.
    h. Once placed in quarantine, reagents cannot be used to test patient or donor samples unless the Medical Director or manager / supervisor indicates that the reagents may be used.
    i. Consult with Manager and Medical Director for the appropriate course of action for

specimens already processed or released during the failure period.

j. Repeat patient testing as necessary and correct results as warranted in the LIS. Notify appropriate clinical staff of any corrected reports.

I. QC Documentation

1. A rack is selected in the Blood Bank computer and the QC results and interpretations are documented as described in the Blood Bank CDMs, *Documentation of the RQ1 and RQ2 Racks* and *Documentation of the RQDAT, RQSCM, RQSCD, RQSCA, GDAT and SALIN Racks*. During computer downtimes, QC is documented on downtime forms, see Transfusion Medicine policy, *Manual Operations - Royal Oak*.

VI. REAGENTS:

A. RQ1 and RQ2
    1. Ortho Bioclone Anti-A, Anti-B, Anti-D and 7% BSA
    2. Gamma Clone Anti-D and the Gamma Clone control
    3. Ortho 3% Affirmagen reverse typing cells

B. RQ60M
    1. Ortho 3% Surgiscreen, 3-cell screen kit
    2. AlbaQ vial 1 and AlbaQ vial 2 (Positive controls)
    3. AlbaQ vial 4 (Negative control)
    4. Ortho Anti-Human Globulin Anti-IgG (Rabbit)
    5. Ortho Coombs Control IgG Coated Reagent Red Blood Cells (Pooled cells)

C. RQLIS
    1. Ortho 3% Surgiscreen, 3-cell screen kit
    2. AlbaQ vial 1 and AlbaQ vial 2 (Positive controls)
    3. AlbaQ vial 4 (Negative control)
    4. Ortho Anti-Human Globulin Anti-IgG (Rabbit)
    5. Ortho Coombs Control IgG Coated Reagent Red Blood Cells (Pooled cells)
    6. Ortho Antibody Enhancement Solution (LISS) or Gamma N-Hance (LISS)

D. RQDAT
    1. Ortho Anti-Human Globulin (Rabbit and Murine Monoclonal) Bioclone, Anti-IgG, -C3d polyspecific
    2. Ortho Anti-Human Globulin Anti-IgG (Rabbit)
    3. Immucor / Gamma Anti-Human Globulin, Anti-C3b, -C3d (Murine Monoclonal) Gamma-clone
    4. Ortho Coombs Control IgG Coated Reagent Red Blood Cells (Pooled cells)

5. Immucor / Gamma Complement Control Cells

E. RQSCD, RQSCA, and RQSCM
    1. AlbaQ vial 1 (Positive controls)
    2. AlbaQ vial 4 (Negative control)
    3. 0.8% SELECTOGEN® Screening Cells

F. GDAT
    1. Gel DAT controls (Positive and Negative)

G. SALIN
    1. Nerl Blood Bank Saline

H. MTS Diluent 2 PLUS™

I. MTS Diluent 2™

J. 0.8% AFFIRMAGEN® Reagent Red Blood Cells

K. 0.8% Panel A Cells

VII. EQUIPMENT AND SUPPLIES:

A. Normal saline

B. 10 x 75 mm or 12 x 75 mm test tubes

C. Calibrated pipette; either manual or electronic.

D. Pipette tips

E. Disposable pipettes

F. Table top centrifuge

G. Automated cell washer

H. MTS incubator

I. MTS centrifuge

J. Ortho Workstation

K. MTS™ Anti-IgG Gel Cards

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

VIII. PROCEDURE:

A. QC of the RQ1 and RQ2 Racks

This QC is performed daily.

1. Evaluate the appearance of each reagent in the rack, see the *Appearance of Reagents* section of this document.

2. Label ten test tubes consecutively.

3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled test tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction
1	1 drop Anti-A	1 drop A_1 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 A_1 cells	Negative
5	1 drop Gamma Clone Anti-D	1 drop Surgiscreen Cell # 1	2+ or greater
6	1 drop Gamma Clone Anti-D	1 drop Surgiscreen Cell # 3	Negative
7	1 drop Gamma Clone control	1 drop Surgiscreen Cell # 2	Negative
8	1 drop Ortho Bioclone Anti-D	1 drop Surgiscreen Cell # 1	2+ or greater
9	1 drop Ortho Bioclone Anti-D	1 drop Surgiscreen Cell # 3	Negative
10	1 drop 7% BSA	1 drop Surgiscreen Cell # 2	Negative

4. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
5. Read and grade the reactions of each tube.
6. Record the graded reactions of each tube in the computer (or on a downtime form, if applicable).
7. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
8. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

B. QC of the RQ60M Rack

This QC is performed daily.

1. Evaluate the appearance of each reagent in the rack, see the *Appearance of Reagents* section of this document.
2. Label seven test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled test 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+	Weak +, 1+, or 2+
2	1 drop Surgiscreen Cell # 2	3 drops of AlbaQ vial 1	0 to 2+	Weak +, 1+, or 2+
3	1 drop Surgiscreen Cell # 3	3 drops of AlbaQ vial 2	0 to 2+	Weak +, 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
7	2 drops Anti-IgG AHG	1 drop IgG coated check cells	NA	Positive (any strength)

4. Proceed as follows:
    a. Tubes # 1 - 6
        i. **DO NOT ADD LISS**. Incubate the test tubes at 37°C for 60 minutes, complete the 60-minute no-LISS antibody screen, and control with IgG coated check cells as described in Transfusion Medicine policy, Antibody Screening.
        ii. Note: Read and record results for 37°C, AHG, and check cells.
    b. Tube # 7
        a. Gently mix the contents of the tube, and centrifuge according to the time calibrated for the centrifuge.
5. Read and grade the reactions of each tube.
6. Record the graded reactions of each tube at each phase in the computer (or on a downtime form, if applicable).
7. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
8. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

C. QC of the RQLIS Rack

This QC is performed each day of use.

1. Evaluate the appearance of each reagent in the rack, see the *Appearance of Reagents* section of this document.
2. Label seven test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled test tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	# Drops of Reagent	Expected Reaction at the 37°C Phase	Expected Reaction at the AHG Pease
1	1 drop Surgiscreen Cell # 1	2 drops AlbaQ vial 1	2 drops LISS	0 to 2+	Weak +, 1+, or 2+
2	1 drop Surgiscreen Cell # 2	2 drops AlbaQ vial 1	2 drops LISS	0 to 2+	Weak +, 1+, or 2+
3	1 drop Surgiscreen Cell # 3	2 drops AlbaQ vial 2	2 drops LISS	0 to 2+	Weak +, 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	Positive (any strength)

4. Proceed as follows:
    a. Tubes # 1 - 6
        i. After adding 2 drops of LISS, incubate the test tubes at 37°C for 15 minutes, complete the LISS antibody screen, and control with IgG coated check cells as described in Transfusion Medicine policy, Antibody Screening.
        ii. Note: Read and record results for 37°C, AHG, and check cells.
    b. Tube # 7

i. Gently mix the contents of the tube, and centrifuge according to the time calibrated for the centrifuge.

5. Read and grade the reactions of each tube.
6. Record the graded reactions of each tube at each phase in the computer (or on a downtime form, if applicable).
7. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
8. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

D. QC of the RQDAT Rack

This QC is performed daily.

1. Evaluate the appearance of each reagent in the rack, see the *Appearance of Reagents* section of this document.
2. Label seven test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled test tubes.
4. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
5. Read, grade, and record the reactions of each tube at each phase in the computer (or on a downtime form, if applicable).
6. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.

7. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction
1	2 drops polyspecific AHG	1 drop IgG coated check cells	Positive (any strength)
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	Positive(any strength)
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

E. QC of the RDSCD, RQSCA, and RQSCM Rack

This QC is performed by each shift.

1. Evaluate the appearance of the SELECTOGEN® cells, the Anti-IgG gel cards, and the positive and negative gel controls (AlbaQ-Chek® Kit); see the *Appearance of Reagents* section of this document.
2. Label four wells of an Anti-IgG gel card, for example:

Well 1	Well 2	Well 3	Well 4	Well 5	Well 6
Pos vs. SCR I	Pos vs. SCR II	Neg vs. SCR I	Neg vs. SCR II		

3. Remove the foil from the applicable wells of the gel card.
4. Add the volume of screen cells, then add the volume of control as specified in the table below.
5. Incubate the gel card at 37°C ± 2°C for 15 minutes, not to exceed 30 minutes.
6. Centrifuge the gel card at 895 ± 25 RPM for 10 minutes if using the MTS centrifuge, or 1032 ± 10 RPM for 10 minutes if using the Ortho Workstation.
7. Read both the front and back of the card for agglutination and grade reactions.
8. Record the reactions in the computer (or on a downtime form, if applicable).
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.

Well #	Volume of Screen Cells	Volume of Control	Expected Reaction
1	50 µL SCR I	25 µL positive gel control (AlbaQ vial 1)	3+ / 4+
2	50 µL SCR II	25 µL positive gel control (AlbaQ vial 1)	3+ / 4+
3	50 µL SCR I	25 µL negative gel control (AlbaQ vial 4)	0
4	50 µL SCR II	25 µL negative gel control (AlbaQ vial 4)	0

F. QC of the GDAT Rack

This QC is performed daily.

1. Evaluate the appearance of the positive and negative gel DAT controls, the Anti-IgG gel cards, and the MTS Diluent 2™; see the *Appearance of Reagents* section of this document.
2. Label two 12 x 75 mm test tubes; e.g., POS DAT CONTROL, and NEG DAT CONTROL.
3. In each of the correspondingly labeled test tubes, prepare a 0.8% cell suspension for each gel DAT control using the MTS Diluent 2™.
    a. Refer to Transfusion Medicine policy, Making a Test Red Cell Suspension.
4. Label two wells of an Anit-IgG gel card, for example:

Well 1	Well 2	Well 3	Well 4	Well 5	Well 6
Pos gel DAT	Neg gel DAT				

5. Remove the foil from the applicable wells of the gel card.
6. Add 50 µL of each gel DAT control to the corresponding Anti-IgG card well.
7. Centrifuge the gel card at 895 ± 25 RPM for 10 minutes if using the MTS centrifuge, or 1032 ± 10 RPM for 10 minutes if using the Ortho Workstation.
8. Read both the front and back of the card for agglutination and grade reactions.
9. Record the reactions in the computer (or on a downtime form, if applicable).
10. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
11. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

Well #	Volume of Gel DAT Control	Expected Reaction
1	50 µL positive gel DAT control	Positive (any strength)
2	50 µL negative gel DAT control	0

G. QC of the SALIN Rack

This QC is performed daily.

1. Label two 12 x 75 mm test tubes; e.g. Boxed saline (and lot number), and Bottled saline (and lot number).
2. Fill each test tube with about 1 mL of saline from the corresponding saline source. Refer to the chart below for the specific bottled saline source that should be used, based on the day of the week.

Day of the Week	Saline Bottle Used for QC
Monday	Station #1
Tuesday	Station #2
Wednesday	Station #3
Thursday	Station #4
Friday	Station #5
Saturday	Water bath in processing room
Sunday	Parent cube for saline bottles

3. Visually inspect each saline sample as described in the *Appearance of Reagents* section of this document.
4. Label two wells of an Anti-IgG gel card, for example:

Well 1	Well 2	Well 3	Well 4	Well 5	Well 6
Boxed vs. SCR I	Bottled vs. SCR II				

5. Remove the foil from the applicable wells of the gel card.
6. Add the volume of SELECTOGEN® screen cells, followed by the volume of each saline source as specified in the table below.

Well #	Volume of Screen Cells	Volume of Saline
1	50 µL SCR I	25 µL Boxed saline
2	50 µL SCR II	25 µL Bottled saline

7. Incubate the gel card at 37°C ± 2°C for 15 minutes, not to exceed 30 minutes.
8. Centrifuge the gel card at 895 ± 25 RPM for 10 minutes if using the MTS centrifuge, or 1032 ± 10 RPM for 10 minutes if using the Ortho Workstation.
9. Read both the front and back of the card for agglutination and grade reactions.
10. Record the reactions in the computer (or on a downtime form, if applicable).
11. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.

12. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

Well #	Volume of Screen Cells	Volume of Saline	Expected Reaction
1	50 µL SCR I	25 µL Boxed saline	0
2	50 µL SCR II	25 µL Bottled saline	0

H. QC of Manual Gel ABO/Rh

This QC is performed only if it is not performed on the ORTHO VISION™ on the current date.

1. Perform forward and reverse ABO/Rh testing of AlbaQ vial 1 and vial 3 as described in Transfusion Medicine policy, Determining the ABO and RhD of Patients Who Are At Least Four Months Old.
2. Read both the front and back of the card for agglutination and grade reactions.
3. Record the reactions on the *Downtime Form: QC of Manual Gel ABO/Rh Testing*.
4. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
5. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

AlbaQ Sample	Test(s) Performed	Expected Results
AlbaQ vial 1	Forward and reverse ABO/Rh	A Negative
AlbaQ vial 3	Forward and reverse ABO/Rh	B Positive

I. QC of Panel A

This QC is performed only when a new box of Panel A is opened, or after the current box of Panel A has been in use for 2 weeks.

1. Using the positive gel control, perform Panel A as described in Transfusion Medicine policy, *Antibody Identification*.
2. Read both the front and back of the card for agglutination and grade reactions.
3. Document the graded reactions on the Panel A antigram for the lot number in use, located on a clipboard at the Problems bench.
4. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
5. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC.

D Antigen	Volume of Panel Cells	Volume of Control	Expected Reaction
Positive	50 µL panel cells	25 µL positive gel control (AlbaQ vial 1)	3+ / 4+
Negative	50 µL panel cells	25 µL positive gel control (AlbaQ vial 1)	0

IX. INTERPRETATION:

A. **Appearance of reagents**: Refer to the *Appearance of Reagents* section of this document 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 rack.

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.

Appearance of Reagents	Performance of Reagents	QC Interpretation
Satisfactory	Satisfactory	Pass
Satisfactory	Unsatisfactory	Fail
Unsatisfactory	Satisfactory	Fail
Unsatisfactory	Unsatisfactory	Fail

X. LIMITATIONS:

A. Strict adherence to procedures and recommended equipment is essential.

B. Proper centrifuge calibration is particularly important to the performance of the MTS centrifuge and Ortho Workstation.

C. 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.

D. 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.

E. Anomalous results may be caused by fresh serum, fibrin, 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.

XI. NOTES:

A. The RQ3 rack is used to perform QC of reagents in the rack as they are received from the manufacturer. For additional information, refer to Transfusion Medicine policy, *Receipt of Critical Blood Bank Reagents and Materials - Royal Oak*.

XII. REFERENCES:

1. AABB, *Technical Manual*, current edition.
2. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
3. Ortho Anti-Human Globulin Bio-Clone, *Qualitative Procedure for the Detection of Cell- Bound Blood Group Antibody and/or Components of Complement*, revised January 2013.
4. College of American Pathologists TRM 31400, *Antisera / Reagent Red Cell QC*, 2020.
5. Micro Typing Systems Instructions For Use – Update Packet, Pub. No. J3308EN, 06/09/2010.
6. Nerl™ Blood Bank Saline Box Packaging, Thermo Fisher Scientific.

Attachments

Panel A Quality Control

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	8/18/2023
	Kristina Davis: Staff Physician	8/14/2023
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	6/21/2023
	Kelly Sartor: Mgr, Division Laboratory	6/21/2023
	Brooke Klapatch: Medical Technologist Lead	6/21/2023