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Quality Control of Blood Bank Reagents

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 to ensure that all reagents are quality tested day of use.

II. SCOPE:

- A. The scope of this document includes the QC of reagents that are generally used in tube testing and manual gel methods.
 1. The QC of the reagents used in the Blood Bank is generally organized in racks. The set up of these racks may vary from site to site. Examples of racks may include but is not limited to the following:
 - a. ABO/Rh Tube Testing Reagents
 - b. 60 Minute-No LISS Indirect Antiglobulin Testing
 - c. LISS Indirect Antiglobulin Testing
 - d. Direct Antiglobulin Tests
 - e. Fetal Cell Screening
- B. Refer to the policies below for information related to QC of reagents for the ORTHO VISION™, antigen typing, fetal cell screening, sickle cell testing, or Kleihauer Betke testing.
 1. Transfusion Medicine policy, [Routine Testing on the Ortho Vision](#)
 2. Transfusion Medicine policy, [Antigen Typing](#)
 3. Transfusion Medicine policy, [Fetal Cell Screening Using the FMH Rapid Screen Kit](#)
 4. Transfusion Medicine policy, [Hemoglobin S Testing of Donor Units](#)
 5. Transfusion Medicine policy, [Hemoglobin S Solubility Testing of Patients - Sickledex Method \(Dearborn Only\)](#)
 6. Transfusion Medicine policy, [QC and Maintenance of the Ortho MTS Gel Workstations.](#)
 7. Transfusion Medicine policy, [Acid Elution by Kleihauer Betke Method - Dearborn Blood Bank](#)

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. 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:** QC period for reagents that are expected to be used each day or most days and is performed daily regardless of whether the reagent is used to test patient or donor samples on that calendar day. For the purposes of this policy this is defined as a 24 hour period determined by testing site i.e. 12am - 12am, 6am - 6am .
- B. **Each day of use:** QC period for reagents that are not expected to be used each day and are tested only on days that the reagent is used to test patient or donor samples. For the purposes of this policy this is defined as a 24 hour elapsed time period i.e. 12am - 12am, 6am - 6am.

V. POLICIES:

A. General

1. The QC for all reagents used in routine testing must be checked for reactivity and specificity on each day of use. The testing must be completed satisfactorily prior to use on all lot numbers of reagents to be used each day.
2. Reagents are to be tested in a manner similar to their usage in patient or product testing.
3. The QC for a given test must be performed in advance of testing patient or donor samples.
4. The QC for all reagents stored in a rack must pass before the reagents in the rack may be used to test patient or donor samples.
5. New reagent lots or additional shipments of an old lot are checked against previous reagent lots or suitable reference material before or concurrently with being placed in service.
6. Records of the quality control testing must be maintained, including results and interpretations, date of testing and identity of personnel performing the testing. These records will be retained in accordance with regulatory requirements.

B. Storage of Reagents

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 (15°C - 30°C) 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.

C. 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 on the applicable QC form as Pass(P) or Fail (F).
 - 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. corQC® Test System :
 - i. corQC Reagent Cells: Do not use if the cells are notably hemolyzed.
 - ii. corQC Reagent Antiserum: Opened vials may become slightly turbid with age. Do not use if Antiserum is markedly turbid.
 - iii. Do not use unlabeled vials.
 - f. Anti-sera, AHG reagents, LISS, Rh controls: Do not use if there is marked turbidity or leaking vials.

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

D. Reagent Expiration Date

1. All reagents and quality control materials 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.

E. 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.

F. 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).
2. 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™.

G. Panel QC Testing

1. It is recommended by the manufacturer that panels should be tested periodically.
2. Ortho Gel Panels (0.8% Ortho® Panel A, B, C)
 - a. Each lot of panel will be tested for each shipment either upon receipt of delivery or when lot is put in to use.
 - b. Open panels should be tested after the box has been in use for at least two weeks, if applicable.
3. Immucor/Werfen Panocells will be tested by tube method upon receipt of a new lot or new shipment of an old lot, prior to use.

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. Immucor Anti-C3b,-C3d reagent
- M. Hemoscience C3 Control Cells
- N. Immucor/Werfen Complement Check Cells
- O. Ortho Antibody Enhancement Solution (OAES, LISS)
- P. Blood Bank Isotonic Saline (0.85 -0.9% NaCl)
- Q. MTS™ Diluent 2 Plus
- R. MTS™ Diluent 2
- S. MTS™ Anti-IgG Gel cards
- T. AlbaQ-Chek® Kit
- U. MTS™ A/B/D Monoclonal and Reverse Grouping Cards
- V. MTS™ IgG Cards
- W. MTS™ A/B/D Forward Typing Cards
- X. MTS™ A/B Typing Cards
- Y. 0.8% AFFIRMAGEN® Reagent Red Blood Cells
- Z. 0.8% Selectogen Screening Cells
- AA. 0.8% Ortho Panel A ,B, C Cells
- AB. 3% Immucor/Werfen Panel Cells
- AC. Gel DAT Controls (Positive and Negative Controls)
- AD. Alba Bioscience AlbaQ-Chek® QC Samples
- AE. CorQC® Test System

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. QUALITY CONTROL

- A. The QC results and interpretations are documented on applicable attached QC 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. Document an internal variance.
 - 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 reagents and controls.
 - d. If the QC fails upon repeat then repeat with fresh opened controls.
 - e. 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.
 - f. 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 supervisor indicates that the reagents may be used.
 - h. Consult with Supervisor 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 BBIS. Notify appropriate clinical staff of any corrected reports.

IX. PROCEDURE:

A. QC of Manual Tube ABO & Rh Reagents

Routine Blood Typing reagents with the exception of A₂ cells must have QC performed daily. Performance of A₂ cells quality control must be performed each day of use.

- 1. Record or confirm reagent lot numbers and expiration dates on the attached *Reagent List for Quality Control Log*.
- 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 and document as (S)atisfactory and (U)nsatisfactory on the attached *Tube ABO/Rh Reagent QC Log* in accordance with Visual Inspection criteria outlined above.

- a. All reagents should be free from turbidity.
- b. Red cell supernatants should be clear/colorless and free from marked hemolysis.
4. Label 14 tubes consecutively.
5. If A₂ cells QC will not be performed label tubes 13 & 14 can be discarded.
Note: QC for A₂ cells will not be performed at Taylor Blood Bank and the Tube ABO/Rh Reagent QC Log for tubes 13 & 14 should be recorded as "NT" - not tested.
6. 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 CorQC Red Cells | 2+ or greater |
| 2 | 1 drop Anti-A | 1 drop B cells | Negative |
| 3 | 1 drop Anti-B | 1 drop CorQC Red Cells | 2+ or greater |
| 4 | 1 drop Anti-B | 1 drop A ₁ cells | Negative |
| 5 | 1 drop Ortho Bioclone Anti-D | 1 drop CorQC Red Cells | 2+ or greater |
| 6 | 1 drop Ortho Bioclone Anti-D | 1 drop Surgiscreen Cell # 3 | Negative |
| 7 | 1 drop 7% BSA | 1 drop CorQC Red Cells | Negative |
| 8 | 1 drop Gamma Clone Anti-D | 1 drop CorQC Red Cells | 2+ or greater |
| 9 | 1 drop Gamma Clone Anti-D | 1 drop Surgiscreen Cell # 3 | Negative |
| 10 | 1 drop Gamma Clone Control | 1 drop CorQC Red Cells | Negative |
| 11 | 1 drop A ₁ cells | 1 drop CorQC AntiSerum | 2+ or greater |
| 12 | 1 drop B cells | 1 drop CorQC AntiSerum | 2+ or greater |
| 13 | 1 drop A ₂ cells | 1 drop CorQC AntiSerum | 1+ or greater |
| 14 | 1 drop A ₂ cells | 1 drop Anti-B | Negative |

7. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
8. Read and grade the reactions of each tube.
9. Use the attached *Tube ABO/Rh Reagent QC Log* to:
 - a. Record the graded reactions of each tube.
 - b. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
 - c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
 - d. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - i. If QC fails for any reason refer to Quality Control section for action steps.

B. QC of the 60 Minute No-LISS Method Reagents

This QC must be performed each day of use.

1. Record or confirm reagent lot numbers and expiration dates on the attached *Reagent List for Quality Control Log*.

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 and document as (S)atisfactory and (U)nsatisfactory on the attached *Manual 60MNL and Tube DAT QC Log* in accordance with Visual Inspection criteria outlined above.
 - a. All reagents should be free from turbidity.
 - b. Red cell supernatants should be clear/colorless and free from marked hemolysis.
4. Label six test tubes consecutively.
5. 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 corQC antiserum | 0 to 2+ | 2+ or greater |
| 2 | 1 drop Surgiscreen Cell # 2 | 3 drops of corQC antiserum | 0 to 2+ | 2+ or greater |
| 3 | 1 drop Surgiscreen Cell # 3 | 3 drops of corQC antiserum | 0 to 2+ | 2+ or greater |
| 4 | 1 drop Surgiscreen Cell # 1 | 3 drops of Saline | Negative | Negative |
| 5 | 1 drop Surgiscreen Cell # 2 | 3 drops of Saline | Negative | Negative |
| 6 | 1 drop Surgiscreen Cell # 3 | 3 drops of Saline | Negative | Negative |

6. 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. Check cell reactions

7. Read and grade the reactions of each tube.

8. Use the attached *Manual 60MNL and Tube DAT QC Log* to:

a. Record the graded reactions of each tube.

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

c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).

d. Interpret the QC as P or F (Pass or Fail) and document accordingly.

i. If QC fails for any reason refer to Quality Control section for action steps.

C. QC of the LISS Method Reagents

This QC is performed each day of use.

1. Record or confirm reagent lot numbers and expiration dates on the attached *Reagent List for Quality Control Log*.

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 and document as (S)atisfactory and (U)nsatisfactory on the attached *Manual Tube LISS QC Log* in accordance with Visual Inspection criteria outlined above.
 - a. All reagents should be free from turbidity.
 - b. Red cell supernatants should be clear/colorless and free from marked hemolysis.
4. Label six test tubes consecutively.
5. 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 Phase |
|--------|-----------------------------|-------------------------|--------------------|-------------------------------------|------------------------------------|
| 1 | 1 drop Surgiscreen Cell # 1 | 2 drops corQC antiserum | 2 drops LISS | 0 to 2+ | 2+ or greater |
| 2 | 1 drop Surgiscreen Cell # 2 | 2 drops corQC antiserum | 2 drops LISS | 0 to 2+ | 2+ or greater |
| 3 | 1 drop Surgiscreen Cell # 3 | 2 drops corQC antiserum | 2 drops LISS | 0 to 2+ | 2+ or greater |
| 4 | 1 drop Surgiscreen Cell # 1 | 2 drops saline | 2 drops LISS | Negative | Negative |
| 5 | 1 drop Surgiscreen Cell # 2 | 2 drops saline | 2 drops LISS | Negative | Negative |
| 6 | 1 drop Surgiscreen Cell # 3 | 2 drops saline | 2 drops LISS | Negative | Negative |

6. 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.
7. Read and grade the reactions of each tube.
8. Use the attached *Manual Tube LISS QC Log* to:
 - a. Record the graded reactions of each tube.
 - b. Evaluate the performance of the reagents by comparing the observed reaction with the expected

reaction.

- c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
- d. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - i. If QC fails for any reason refer to Quality Control section for action steps.

D. QC of the DAT Tube Reagents

This QC must be performed each day of use.

1. Record or confirm reagent lot numbers and expiration dates on the attached *Reagent List for Quality Control Log*.
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 and document as (S)atisfactory and (U)nsatisfactory on the attached *Manual 60MNL and Tube DAT QC Log* in accordance with Visual Inspection criteria outlined above.
 - a. All reagents should be free from turbidity.
 - b. Red cell supernatants should be clear/colorless and free from marked hemolysis.
4. Label seven test tubes consecutively.
5. 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 | 2 drops polyspecific AHG | 1 drop IgG coated check cells | 1+ 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 | 1+ 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. Gently mix the contents of each tube.
7. Centrifuge all tubes except tubes 2,5,6 according to the time calibrated for the centrifuge.
8. Incubate tubes 2, 5, 6 for 5 minutes at room temperature.
9. Read and grade reactions of each tube.
10. Use the attached *Manual 60MNL and Tube DAT QC Log* to:
 - a. Record the graded reactions of each tube.

- b. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
- c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
- d. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - i. If QC fails for any reason refer to Quality Control section for action steps.

E. QC of the Manual Gel Screen Cells

This QC must be performed each day of use.

1. Record or confirm the lot numbers and expiration dates of the SELECTOGEN® cells, the Anti-IgG gel cards, and the AlbaQ-Chek® Controls on the attached *Reagent List for Quality Control Log*.
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 reagents and document as (S)atisfactory and (U)nsatisfactory on the attached *Manual Gel Screen and Gel DAT QC Log* in accordance with Visual Inspection criteria outlined above.
4. 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 | | |

5. Remove the foil from the applicable wells of the gel card.
6. Add the volume of screen cells, then add the volume of control as specified in the table below.

| 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 3 or 4) | 0 |
| 4 | 50 µL SCR II | 25 µL negative gel control (AlbaQ vial 3 or 4) | 0 |

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. Use the attached *Manual Gel Screen and Manual Gel DAT QC Log* to:
 - a. Record the graded reactions of each tube.
 - b. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
 - c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
 - d. Interpret the QC as P or F (Pass or Fail) and document accordingly.

- i. If QC fails for any reason refer to Quality Control section for action steps. Record the reactions on the *Manual Gel Screen and Gel DAT QC Log*.

F. QC of the Manual Gel DAT (Direct Antiglobulin Test)

This is used to QC manual gel anti-IgG cards and MTS™ Diluent 2 used in manual gel DAT& manual gel crossmatching for each day of use.

1. Record or confirm reagent lot/unit numbers and expiration dates for the positive and negative gel DAT controls, the Anti-IgG gel cards, and the MTS Diluent 2™ on the attached *Reagent List for Quality Control Log*.
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 reagents and document as (S)atisfactory and (U)nsatisfactory on the attached *Manual Gel Screen and Gel DAT QC Log* in accordance with Visual Inspection criteria outlined above.
4. Label two 12 x 75 mm test tubes; e.g., POS DAT CONTROL, and NEG DAT CONTROL.
5. 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](#).
6. Label two wells of an Anti-IgG gel card, for example:

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

7. Remove the foil from the applicable wells of the gel card.
8. Add 50 µL of each gel DAT control to the corresponding Anti-IgG card well as per table below.

| Well # | Volume of Gel DAT Control | Expected Reaction |
|--------|--------------------------------|-------------------|
| 1 | 50 µL positive gel DAT control | 1+ or greater |
| 2 | 50 µL negative gel DAT control | 0 |

9. 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.
10. Read both the front and back of the card for agglutination and grade reactions.
11. Use the attached *Manual Gel Screen and Manual Gel DAT QC Log* to:
 - a. Record the graded reactions of each tube.
 - b. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
 - c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
 - d. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - i. If QC fails for any reason refer to Quality Control section for action steps. Record the reactions on the *Manual Gel Screen and Gel DAT QC Log*.

G. QC of Manual Gel ABO/Rh

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

Exception: Taylor Blood Bank where this QC is performed daily.

1. Record or confirm reagent lot/unit numbers and expiration dates for the MTS A/B/D Monoclonal and Reverse Grouping Cards, 0.8% Affimagens and the MTS Diluent 2 Plus™ on the attached *Reagent List for Quality Control Log*.
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 reagents and document as (S)atisfactory and (U)nsatisfactory on the attached *Manual Gel ABO/Rh QC Log* in accordance with Visual Inspection criteria outlined above.
4. Perform forward and reverse ABO/Rh testing of AlbaQ vial 1 and vial 3 as described in Transfusion Medicine policy, [ABO/Rh Typing](#).

| 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 |

5. 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.
6. Read both the front and back of the card for agglutination and grade reactions.
7. Use the attached *Manual Gel ABO/Rh QC Log* to:
 - a. Record the graded reactions of each tube.
 - b. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
 - c. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
 - d. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - i. If QC fails for any reason refer to Quality Control section for action steps. Record the reactions on the *Manual Gel Screen and Gel DAT QC Log*.

H. QC of Ortho Panels

This QC is performed only when a new lot # is received/opened for use, or after the current box of panel has been in use for 2 weeks.

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

1. Record the lot number and expiration dates for the AlbaQ Controls and Panel Cells on the attached *0.8% Panel QC Log*.
2. Evaluate the appearance of the reagents and document as (S)atisfactory and (U)nsatisfactory in the appropriate column on the log. Refer to policy; Appearance of Reagents.
3. Label two 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 |
|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----------------|-----------------|

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

| Panel | Positive 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 |

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 front and back of the card for agglutination and grade reactions. Refer to Transfusion Medicine Policy, [Reading, Grading and Recording Test Reaction](#).
9. Record the reactions on the appropriate panel antigram sheet for the lot# being tested.
10. 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.
11. Use the attached 0.8% *Panel QC Log* to:
 - a. Document the performance of the expected reactions in the appropriate columns.
 - b. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
 - c. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - i. If QC fails for any reason refer to Quality Control section for action steps.
12. Attach the antigram to the 0.8% *Panel QC Log*.
13. All panels will be labeled appropriately to indicate the QC status for the lot/shipment in accordance with site specific reagent receipt policies. The attached *Panel QC Sticker* may be used for this purpose.

I. QC of the Immucor/Werfen Panocells

This QC is performed only when a new lot # is received/opened for use.

1. Preparation of the Positive Control

- a. Obtain a new 10 mL vial of Gamma Clone® control.
- b. Remove 100 µL from the Gamma Clone® control and discard
- c. Add 100 µL of the Gamma Clone Anti-D reagent to the vial of Gamma Clone Control.
- d. Thoroughly mix the contents of the vial.
- e. Label the freshly prepared Positive Tube 3% Panel Control with the attached Diluted Anti-D Label . The new expiration date is the shorter of the reagent expiration dates. This material will be stored at 2°C to 8°C when not in use.

- i. Check to confirm that the positive tube control reacts as expected using 3% Surgiscreen® cells.
- ii. Label four test tubes consecutively.
- iii. 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 37°C | Expected Reaction @ AHG |
|------|---------------------------|----------------------------|--------------------|---------------------------|-------------------------|
| 1 | 2 drops of Diluted Anti-D | 1 drop Surgiscreen cell #1 | 2 drops LISS | 0 to 2+ | 1+ or greater |
| 2 | 2 drops of Diluted Anti-D | 1 drop Surgiscreen cell #2 | 2 drops LISS | 0 to 2+ | 1+ or greater |
| 3 | 2 drops of Diluted Anti-D | 1 drop Surgiscreen cell #3 | 2 drops LISS | Negative | Negative |

2. If the diluted Anti-D reacts as expected, proceed to step 3.

- a. If the diluted Anti-D was insufficiently reactive against either of Surgiscreen® cells #1 or #2, transfer an additional volume (e.g., additional 25 µL) of Gamma Clone® Anti-D reagent to the prepared vial and repeat steps 5-6.

3. **Performing QC of the Panocells.**

- a. Record the lot number and expiration dates for the Anti-D, Gamma Clone Control reagents and Panel Cells on the attached 3.0% *Panel QC Log*.
- b. Evaluate the appearance of the reagents and document as (S)atisfactory and (U)nsatisfactory in the appropriate column on the log. Refer to policy; Appearance of Reagents.
- c. Remove 1 copy of the panel antigram. Write tech initials, date of QC and phase of testing (37, AHG and CC).
- d. Identify the following two cells that will be used for QC:
 - i. Negative control: 1 cell negative for D antigen.
 - ii. Positive control: 1 cell positive for D antigen, preferably heterozygous (R1r, Ror)
- e. Label tubes with the cell numbers to be tested.
- f. Add two drops of the diluted Anti-D to each tube.
- g. Add one drop of the cells to the corresponding tube.
- h. Add two drops of LISS to each tube.
- i. Incubate the test tubes at 37°C for 15 minutes. Incubation times may be extended up to but must not exceed 30 minutes.
- j. Remove the test tubes from the incubator and centrifuge them according to the calibrated time of the centrifuge.

- k. Gently resuspend the cell button of each tube. Read, grade, and record the reactions on the panel antigram for the 37°C phase.
- l. Wash the test tubes in an automatic cell washer for 4 cycles.
 - i. Alternatively, the test tubes can be manually washed by hand 4 times, decanting completely after each wash.
- m. Add 2 drops of Anti-IgG AHG to the washed test tubes and gently agitate to resuspend the cell button.
- n. Centrifuge the test tubes according to the calibrated time of the centrifuge.
- o. Gently resuspend the cell button of each tube. Read, grade, and record the reactions on the panel antigram for the AHG phase.
- p. Add IgG coated check cells to any of the test tubes that are negative.
- q. Centrifuge the test tubes according to the calibrated time of the centrifuge.
- r. Gently resuspend the cell button of each tube. Read, grade, and record the reactions on the antigram for the check cell phase (CC).
- s. Evaluate the performance of the reagents by comparing the observed reaction with the expected reactions such that the positive D antigen cell reacted positively (1+ or greater) and the D negative antigen cell reacted negatively.
- t. Use the attached 3.0% *Panel QC Log* to:
 - i. Document the performance of the expected reactions in the appropriate columns.
 - ii. Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
 - iii. Interpret the QC as P or F (Pass or Fail) and document accordingly.
 - A. If QC fails for any reason refer to Quality Control section for action steps.
- u. Attach the antigram to the 3% *Panel QC Log*.
- v. All panels will be labeled appropriately to indicate the QC status for the lot/shipment in accordance with site specific reagent receipt policies. The attached *Panel QC Sticker* may be used for this purpose.

X. 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 |

XI. LIMITATIONS:

- A. Strict adherence to procedures and recommended equipment is essential.
- B. Appropriate centrifugation time is determined for and posted on each centrifuge.
- C. Proper centrifuge calibration is particularly important to the performance of the MTS centrifuge and Ortho Workstation.
- D. When testing reagent antiserum, a red cell known to be negative for the corresponding antigen and a red cell known to be heterozygous positive (when appropriate) for the corresponding antigen must be tested.
- 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, 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.

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

[0.8% Panel QC Log \(rev.10/31/2024\)](#)
[3% Panel QC Log \(rev. 10/31/2024\)](#)
[Antigen Typing Downtime Form \(rev. 08/01/2023\)](#)
[DILUTED ANTI D LABEL \(rev. 10/30/2024\)](#)
[Fetal Cell Screen QC Log \(rev. 10/31/2024\)](#)
[Manual 60MNL and Tube DAT QC Log \(rev. 10/31/2024\)](#)

Manual Gel ABORH QC Log (rev 10/31/2024)
Manual Gel Screen and Gel DAT QC Log (rev. 10/31/2024)
Manual Sickle Cell Screen QC Log (rev. 10/31/2024)
Manual Tube ABO/RH QC Log (rev. 10/31/2024)
Manual Tube LISS QC Log (rev. 10/31/2024)
Panel QC Sticker (rev. 10/30/24)
REAGENT LIST FOR QUALITY CONTROL DOCUMENTATION (revised 10/30/24)

Approval Signatures

| Step Description | Approver | Date |
|---|--|------------|
| | Ann Marie Blenc: System Med Dir, Hematopath | 10/31/2024 |
| | John Pui: Chief, Pathology | 10/31/2024 |
| | Masood Siddiqui: Staff Pathologist | 10/31/2024 |
| | Kristina Davis: Staff Physician | 10/31/2024 |
| | Jeremy Powers: Chief, Pathology | 10/31/2024 |
| | Hassan Kanaan: OUWB Clinical Faculty [RJ] | 10/31/2024 |
| | Ryan Johnson: OUWB Clinical Faculty | 10/31/2024 |
| | Muhammad Arshad: Chief, Pathology | 10/31/2024 |
| Policy and Forms Steering Committee (if needed) | Kelly Sartor: Mgr, Division Laboratory | 10/31/2024 |
| | Katherine Persinger: Mgr, Laboratory | 10/31/2024 |
| | Suzanne Chahine: Medical Technologist Lead [FB] | 10/31/2024 |
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne