PROCEDURE
Corewell Health East - Quality Control of Blood Bank Reagents - All Beaumont Hospitals

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

This document will 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.

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. 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

D. Any testing to be performed at a given site must have completed validation and approval for testing at the given site.
E. 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 procedure, Routine Testing on the Ortho Vision
   2. Transfusion Medicine procedure, Antigen Typing
   3. Transfusion Medicine procedure, Fetal Cell Screening Using the FMH Rapid Screen Kit
   4. Transfusion Medicine procedure, Hemoglobin S Testing of Donor Units
   5. Transfusion Medicine procedure, Hemoglobin S Solubility Testing of Patients - Sickledex Method (Dearborn Only)
   6. Transfusion Medicine procedure, Acid Elution by Kleihauer Betke Method - Dearborn Blood Bank

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.
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 to respond appropriately.

3. 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 procedure 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 procedure this is defined as a 24-hour elapsed time period i.e. 12am - 12am, 6am - 6am.

4. Reagent/Equipment Needed

1. ORTHO Anti-A Bioclone
2. ORTHO Anti-B Bioclone
3. ORTHO Anti-D Bioclone
4. Werfen/Immucor Gammaclone Anti-D or Series 4
5. ORTHO 7%Bovine Serum Albumin
6. Werfen/Immucor Gammaclone Rh Control
7. ORTHO 3% Affirmagen cells (A1 and B Cells)
8. ORTHO A2 Cells
9. ORTHO 3% Surgiscreen cells (Screening cells 1, 2 & 3)
10. ORTHO Coombs Control IgG Coated reagent red blood cells (CC)
11. ORTHO Anti-Human Globulin IgG reagent (IgG)
12. ORTHO Anti-Human Globulin IgG, C3d Polyspecific (Poly AHG)
13. ORTHO Anti-C3b,-C3d reagent
14. Werfen/Immucor Anti-C3b,-C3d reagent
15. Hemoscience C3 Control Cells
16. Werfen/Immucor Complement Check Cells
17. ORTHO Antibody Enhancement Solution (OAES, LISS)
18. Werfen/Immucor Gamma N-HANCE
19. Blood Bank Isotonic Saline (0.85 -0.9% NaCl)
20. ORTHO MTS™ Diluent 2 Plus
21. ORTHO MTS™ Diluent 2
22. ORTHO MTS™ Anti-IgG Gel cards

23. ORTHO MTS™A/B/D Monoclonal and Reverse Grouping Cards
24. ORTHO MTS™ IgG Cards
25. ORTHO MTS™A/B/D Forward Typing Cards
26. ORTHO 0.8% AFFIRMAGEN® Reagent Red Blood Cells
27. ORTHO 0.8% Selectogen Screening Cells
28. ORTHO Panel A, B, C Cells
29. Werfen/Immucor Panel Cells
30. Gel DAT Controls (Positive and Negative Controls)
31. ORTHO™ Daily QC Simulated Whole Blood Quality Control Kit
32. Werfen/Immucor CorQC® Test System
33. 0.9% normal saline
34. 10 x 75 mm or 12 x 75 mm test tubes
35. Calibrated pipette; either manual or electronic
36. Pipette Tips
37. Disposable pipettes
38. Table top centrifuge
39. Serofuge
40. Automated cell washer
41. MTS incubator/MTS centrifuge and/or MTS Ortho Workstation

5. Quality Control

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:
        1) The gel matrix is absent.
        2) The liquid level in the microtube is at or below the top of the gel matrix.
        3) The cards show signs of drying, discoloration, bubbles, crystals, or other artifacts.
        4) 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. ORTHO™ Daily QC vials: Do not use if obviously discolored or hemolyzed. Slight discoloration of the supernatant is normal.
    e. corQC® Test System:
        1) corQC® Reagent Cells: Do not use if the cells are notably hemolyzed.
        2) corQC® Reagent Antiserum: Opened vials may become slightly turbid with age. Do not use if Antiserum is markedly turbid.
        3) 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. Once opened, the ORTHO™ Daily QC vials expire on the shorter of 14 days from the open date or the original expiration date. When opened, the “open date”, the technologist’s initials, and the new expiration date shall be recorded on the vials directly or on an affixed label.
3. 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.
    a. 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. An internal variance should also be submitted.

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. For sites that keep an open bottle of MTS Diluent 2 at room temperature for manual testing, please use the following guidelines:
    a. The Blood Bank will maintain two bottles of MTS Diluent 2™ with dispensers (with the same diluent lot number in each bottle).
    b. These bottles are rotated every 24 hours (so that one bottle is in use at room temperature and the other is stored at 2°C to 8°C).

G. Panel QC Testing
1. Ortho Gel Panels:
    a. It is recommended by the manufacturer that panels should be tested periodically.

b. Each lot/shipment of panels will be tested either upon receipt of delivery or when lot is put in to use.
c. Open panels should be tested after the box has been in use for at least two weeks, if applicable.

2. 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.

H. QC Documentation: QC results and interpretations are documented on applicable attached QC forms.

I. 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.

6. Calibration

All equipment used must be up to date on required maintenance and calibration.

7. 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 which: fail visual inspection, have expired, will expire prior to next daily QC, or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of each reagent and document as (S)atisfactory or (U)nsatisfactory on the attached Tube ABO/Rh Reagent QC Log in accordance with Visual Inspection criteria outlined above.
4. Label 14 tubes consecutively.
a. If A2 cells QC will not be performed label tubes 13 & 14 can be discarded.
1) 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.
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	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

6. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
7. Read and grade the reactions of each tube.
8. 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.
        1) 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 which: fail visual inspection, have expired, will expire prior to next daily QC, or which lack sufficient volume for a full day of testing.
3. Evaluate the appearance of each reagent and document as (S)atisfactory or (U)nsatisfactory on the attached Manual 60MNL and Tube DAT QC Log in accordance with Visual Inspection criteria outlined above.
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 / Reagent	# Drops / Reagent or QC material	Expected Reaction at 37°C Phase	Expected Reaction at 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
      1) 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 procedure, Antibody Screening.
      2) 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 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.
      1) If QC fails for any reason refer to Quality Control section for action steps.

C. QC of 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 or (U)nsatisfactory on the attached *Manual Tube LISS QC Log* in accordance with Visual Inspection criteria outlined above.

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 / Reagent	# Drops / Reagent or QC Material	# Drops / Reagent	Expected Reaction at 37°C Phase	Expected Reaction at 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
      1) 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 procedure, Antibody Screening.
      2) 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.
      1) 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 or (U)nsatisfactory on the attached *Manual Tube DAT QC Log* in accordance with Visual Inspection criteria outlined above.
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 / Reagent	# Drops / 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 according to the time calibrated for the centrifuge.
8. Read and grade reactions of each tube.
   a. Note: Weak complement reactions may be enhanced by 5 minute room temp incubation.
9. Use the attached *Manual 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.
      1) If QC fails for any reason refer to Quality Control section for action steps.

E. **QC of the Screen Cells in Manual Gel**: 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 ORTHO™ Daily QC 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		
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 Ortho Daily QC (Ortho Daily QC vial 4)	3+ / 4+
2	50 µL SCR II	25 µL positive gel control (Ortho Daily QC vial 4)	3+ / 4+
3	50 µL SCR I	25 µL negative gel control (Ortho Daily QC vial 1)	0
4	50 µL SCR II	25 µL negative gel control (Ortho Daily QC vial 1)	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.
        1) 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 or (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 procedure, Making a Test Red Cell Suspension.
6. 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				

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.
        1) 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, Trenton, and Wayne Blood Banks 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% Affirmagens, ORTHO™ Daily QC, 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 or (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 ORTHO™ Daily QC vial 3 and vial 4 as described in Transfusion Medicine procedure, ABO and Rh Typing.

ORTHO Daily QC Sample	Test(s) Performed	Expected Results
ORTHO Daily QC Vial 3	Forward and reverse ABO/Rh	A Positive
ORTHO Daily QC Vial 4	Forward and reverse ABO/Rh	B Negative

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.
        1) 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 0.8% 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 can be performed manually or performed on the Ortho Vision® in accordance with Corewell Health East - Routine Testing on the ORTHO VISION Analyzer - All Beaumont Hospitals .

1. Record the lot number and expiration dates for the ORTHO™ Daily QC Controls and Panel Cells on the attached *0.8% Panel QC Log*.
2. Evaluate the appearance of the reagents and document as (S)atisfactory or (U)nsatisfactory in the appropriate column on the log. Refer to section above: Appearance of Reagents.
3. For manual testing: 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	Ortho Daily QC Vial 4	3+/4+ (D Pos cells)	Anti-D
B	Ortho Daily QC Vial 2	3+/4+ (c Pos cells)	Anti-c
C	Ortho Daily QC Vial 3	3+/4+ (Fy^a Pos cells)	Anti-Fy^a

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 front and back of the card for agglutination and grade reactions. Refer to Transfusion Medicine Procedure, Corewell Health East - Reading, Grading, and Recording Test Reactions - Blood Bank - All Beaumont Hospitals.
10. Record the reactions on the appropriate panel antigram sheet for the lot# being tested.
11. 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.
12. 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.
        1) If QC fails for any reason refer to Quality Control section for action steps.
13. Attach the antigram to the *0.8% Panel QC Log*.
14. 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 3% Panels: This QC is performed only when a new lot # is received/opened for use. (For ORTHO Panels only, QC is also performed after the current lot/shipment of panel has been in use for 2 weeks)

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.
   1) Check to confirm that the positive tube control reacts as expected using 3% Surgiscreen® cells.
   2) Label four test tubes consecutively.
   3) Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube	# Drops of QC Material	# Drops of Reagent	# Drops of Reagent	Expected Reaction at 37ºC	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 3% Panels**.
   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 section above: 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:
      1) Negative control: 1 cell negative for D antigen.
      2) 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.

1) 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:
    1) Document the performance of the expected reactions in the appropriate columns.
    2) Document the performance of the reagents as S or U (Satisfactory or Unsatisfactory).
    3) 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.

8. Results/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

9. 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.

10. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

11. 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.

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13. Keywords

Not Set