Status **Scheduled** PolicyStat ID **15134961**

Beaumont

Origination	3/7/2024
Last Approved	2/6/2024
Effective	3/7/2024
Last Revised	2/6/2024
Next Review	2/5/2026

Document Contact	Teresa Lovins: Supv, Laboratory
Area	Laboratory-Blood Bank
Applicability	Troy

Quality Control of the Manual Gel System

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document provides the Blood Bank staff with policies and instructions relating to the quality control (QC) of the reagents used in the Ortho Clinical Diagnostics® (OCD) ID-Micro Typing System™ (manual gel system).

II. CLINICAL SIGNIFICANCE:

A. Quality control 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.
    1. These regulations require that each cell used for antibody detection must be checked each day of use.
    2. 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.
    3. OCD recommends testing each gel card lot on each day of use with known antigen positive and antigen negative red blood cells.
    4. These requirements are satisfied as described throughout this document

B. QC testing is performed to establish that the proper functioning of materials, equipment, and methods occurs during operation.
    1. 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.

2. All technologists are not required to perform QC daily, but all should participate in the performance of QC on a regular basis.
3. 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.

III. SCOPE:

A. The QC of the reagents used in the Blood Bank is organized by computer racks. The scope of this document includes the QC of reagents that are used in manual gel testing, and that are organized as described below:

Computer Rack	Contains Reagent to Perform the Following Procedures
TQGSR	Manual gel antibody screen
TQGXM	Gel crossmatches

IV. POLICIES:

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

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

C. **Storage of Reagents**

1. The MTS™ gel cards should be stored in an upright position at 2°C to 25°C.
2. The reagent screen cells should be stored at 2°C to 8°C.
    a. Prolonged exposure of the 0.8% pre-diluted cells to both light and room temperature conditions can cause non-specific reactivity, the Blood Bank will take steps to minimize these conditions.
    b. The 0.8% screening cells will be stored in the original, manufacturer's box and should be brought to room temperature for approximately 15 minutes before testing. They should be returned to the refrigerator when not in use.
    c. Prolonged exposure of the pre-diluted 0.8% Ortho® panel cells to both light and room temperature conditions can cause non-specific reactivity, the Blood Bank will take steps to minimize these conditions. T
    d. The 0.8% panel cells will be stored in the original, manufacturer's box and should be returned to the refrigerator as soon as possible after use. These panel cells should be brought to room temperature for approximately 15 minutes before use.
    e. 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.
    f. Use of the MTS diluent™ within 2 weeks of the date that it is opened minimizes the potential for contamination.

D. **Panel QC Testing**

1. Upon opening all panels for the first time, the open date and technologist's initials will be documented on the panel container.
2. It is recommended by the manufacturer that panels should be tested periodically with weak antibodies. Therefore, the day shift 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.
    a. If the 0.8% Ortho® Panel A has been in use for two weeks, this QC will be performed again, and another sticker will be documented and affixed to the box.
    b. Alternate panels (e.g., the Ortho® 3% panel, the Ortho® 0.8% panel B, and the Immucor® panels) are used for additional confirmatory testing and are subject to internal controls (inclusion of reactive and non-reactive cells) during routine use. Therefore, additional QC testing is not performed.

E. **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 the applicable downtime form) as satisfactory (S) or unsatisfactory (U).
    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.
        i. Do not use gel cards if:
            a. the gel matrix is absent.
            b. the liquid level in the microtube is at or below the top of the gel matrix.
            c. the cards show signs of drying, discoloration, bubbles, crystals, or other artifacts.
            d. foil seals appear damaged or opened.
    c. Reagent red cells: Do not use the reagent red cells if discoloration or visible signs of hemolysis are present.
    d. Positive and negative gel controls: Do not use if there is any evidence of discoloration, turbidity, or signs of contamination.

F. **Failing QC of Reagents**

1. The routine QC of reagents is interpreted as passing or failing based on the expected results and the visual inspection.
2. If the QC fails for any reason:
    a. Document the Transfusion Medicine form, *Reagent and Equipment*

Problems Log.

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.

d. The QC will be repeated with newly opened controls.

e. If the QC fails upon repeat with the same lot number, then the QC will be tested with a different lot number of reagent if possible.

i. 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 and QC will be performed with a different lot number.

ii. 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.

G. **Failing QC of the 0.8% Ortho® Panel A**

1. Document Transfusion Medicine form, *Reagent and Equipment Problems Log*.
2. Test results of patient or donor samples may not be released unless / until QC passes.
3. The QC will be repeated with a new vial of the Positive Gel Control.
4. The QC will be repeated with a new box of Panel A.
5. 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.
6. 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.

a. Perform QC with a different lot number.

b. If the QC fails for each box and lot of Panel A, Panel B can be used as our primary panel after QC testing has been performed on Panel B.

c. 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.

V. REAGENTS, EQUIPMENT, AND SUPPLIES:

A. MTS™ Diluent 2 Plus

B. MTS™ Diluent 2

C. MTS™ Anti-IgG Gel cards

D. Positive gel control and negative gel control, prepared as described in Transfusion Medicine policies, *Preparation of Quality Controls*.

E. AlbaQ-Chek® Kit

F. MTS™ A/B/D Monoclonal and Reverse Grouping Cards
G. MTS™ IgG Cards
H. 0.8% AFFIRMAGEN® Reagent Red Blood Cells
I. 0.8% Selectogen® Screening Cells
J. 0.8% Ortho® Panel A Cells
K. 3% Surgiscreen® Screening Cells
L. Calibrated pipette
M. Pipette tips
N. Plastic 12 x 75mm test tubes
O. MTS™ incubator
P. MTS™ centrifuge

VI. PROCEDURE:

A. Performing the QC of the TQGSR Rack

1. Evaluate the appearance of the 2-cell Selectogen® screen cells, the IgG gel cards, and the positive and negative gel controls for acceptability.
2. Label 4 wells of an IgG gel card
    a. Pos vs. SCR I
    b. Neg vs. SCR I
    c. Pos vs. SCR II
    d. 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.
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.
7. Read both front and back of the card for agglutination and grade reactions.
8. Record the reactions in the computer.
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 (pass or fail).

Well #	Volume of Screen Cells	Volume of Control	Expected Reaction Strength
1	50 µL SCR I	25 µL POS gel control	w+ or 1+ or 2+

2	50 µL SCR I	25 µL NEG gel control	0
3	50 µL SCR II	25 µL POS control	w+ or 1+ or 2+
4	50 µL SCR II	25 µL NEG control	0

B. Performing the QC of the TQGXM Rack

1. Evaluate the appearance of the Surgiscreen® cells, the IgG gel cards, the MTS Diluent 2™, and the positive gel control for acceptability.
2. Label three 12 x 75 mm test tubes; e.g., SCRI, SCRII, and SCRIII.
3. In each of the correspondingly labeled tubes, dilute the 3% Surgiscreen® cells to 0.8% with the MTS Diluent 2™.
4. Label 3 wells of an IgG gel card
    a. Pos vs. SCR I
    b. Pos vs. SCR II
    c. Pos vs. SCR III
5. Remove the foil from the applicable wells of the gel card.
6. Add the volume of diluted screen cells, then add the volume of the positive gel control as specified in the table.
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.
9. Read both front and back of the card for agglutination and grade reactions.
10. Record the reactions in the computer.
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 (pass or fail).
13. *Note: The positive gel control (consisting of diluted Anti-D) is expected to be non-reactive with SCR III (SCR III is Rh(D) negative). So the term “positive gel control” is a misnomer in this case; it is expected to be non-reactive against SCR III.

Well #	Volume of Screen Cells	Volume of Control	Expected Reaction Strength
1	50 µL SCN I	25 µL POS gel control	w+ or 1+ or 2+
2	50 µL SCN II	25 µL POS gel control	w+ or 1+ or 2+
3	50 µL SCN III	25 µL POS gel control	0

C. Performing QC of the 0.8% Ortho Panel A

1. This QC is performed by the day shift, before (or within 2 days) of the date when a new box of 0.8% Ortho® Panel A is opened.

2. This QC is also performed if the current panel has been in use for 2 weeks.
3. Evaluate the appearance of the 0.8% Ortho® Panel A and the positive gel control (POSGC).
4. Test the positive gel control against the entire 0.8% Ortho® Panel A.
5. Read both front and back of the card for agglutination, grade the reactions, and record the reactions on a copy of the antigram.
6. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
7. Document 3 stickers (the 0.8% Ortho® Panel A QC) with the following information:
    a. POSGC lot number and expiration date
    b. Appearance of the reagents as S or U (satisfactory or unsatisfactory)
    c. Performance of the reagents as S or U (satisfactory or unsatisfactory)
    d. QC Interpretation as P or F (pass or fail)
    e. Initial and date
    f. Affix one copy of the documented sticker to the antigram, one to the white panel rack, and the other to the panel box.
    g. Place the antigram in the 0.8% Panel A Antigram QC Binder.
    h. Document the 0.8% Ortho® Panel A sheet with a check mark to indicate that the QC was performed when the new box was opened and that the QC passed.
    i. If a 0.8% Ortho® Panel A has been in use for 2 weeks, repeat QC testing.
    j. Affix 1 sticker to the panel box.
    k. Affix 1 sticker to the white panel rack.
    l. Affix 1 sticker to the same antigram on which the QC was documented (2 weeks prior).

Rh(D) Antigen	Volume Panel Cells	Volume of Control	Expected Reactions
Rh(D) POS	50 µL panel cells	25 µL of POS gel control	w+ or 1+ or 2 +
Rh(D) NEG	50 µL panel cells	25 µL of POS gel control	0

VII. INTERPRETATIONS:

A. **Performance of Reagents**

1. The performance of the reagent is evaluated by comparing the observed reactions with the expected reactions.
    a. The performance is considered satisfactory if the observed reactions match the expected reactions.
    b. The performance is considered unsatisfactory if the observed reactions do

not match the expected reactions.

VIII. LIMITATIONS:

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

B. Proper centrifuge calibration is important to the performance of the MTS Centrifuge.

C. Variations in red blood cell concentration can markedly affect the sensitivity of test results.

1. 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.
2. 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.
3. 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.
4. Anomalous results may be caused by fresh serum, fibrin, or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube.
5. 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.

IX. REFERENCES:

1. College of American Pathologists TRM 31400, Antisera / Reagent Red Cell QC, 2010
2. Micro Typing Systems Instructions For Use – Update Packet, Pub. No. J3308EN, 06/09/2010
3. AABB, *Technical Manual*, current edition.
4. AABB, *Standards for Blood Banks and Transfusion Services,* current edition.

Attachments

Downtime QC form TQGSR and TQGXM.docx

Equipment Alarms and Temp Deviations.pdf

PanelA.QCsticker.doc

Approval Signatures

Step Description	Approver	Date

	Vaishali Pansare: Chief, Pathology	2/6/2024
	Ryan Johnson: OUWB Clinical Faculty	1/31/2024
Policy and Forms Steering Committe (if needed)	Teresa Lovins: Supv, Laboratory	1/30/2024
	Teresa Lovins: Supv, Laboratory	1/30/2024

Applicability

Troy