# PROCEDURE

**Title:** Quality Control for the Gel System

**Procedure #:** 2015BLOODBANK15

Institution: Highlands Regional Medical Center

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Title: Laboratory Administrative Director

Accepted by: _____ Date: 6-5-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 9/1/2010

Review of procedure every two years

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Discontinued testing date: _____

# PROCEDURE 15 QC

## Quality Control of MTS™ Manual Gel Test System Reagents

## Principle

The purpose of daily quality control (QC) in the blood bank is to confirm the reliability of the test system. The test system includes reagents, procedures, and equipment. Testing known samples is an accepted method of quality control.

The procedures used with the reagents described are based on the principle of hemagglutination. These procedures are applicable to selected gel card applications. Directions for quality control of gel test reagents are outlined in the Instructions for Use for each MTS™ reagent.

**Procedures are for manual testing only. When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer. Laboratories must follow their approved validation procedures to demonstrate compatibility of ORTHO® Confidence Antibody with other test methods, either manual or automated.**

## Reagents

- Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Card.
- Reagent red blood cells for antibody detection comprised of human red blood cells as:
  - 0.8%, ready for use in MTS™ Anti-IgG testing
  - 3%, to be prepared as 0.8% for use in MTS™ Anti-IgG testing:
- MTS™ Diluent 2™ (a hypotonic buffered saline solution used to prepare 0.8% red blood cells for testing in Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Cards)
- MTS™ A/B/D Monoclonal and Reverse Grouping Card™ [sequential Anti-A (BIRMA-1 Clone), Anti-B (LB-2 Clone), Anti-D (MS-201 Clone), Control Gel, Buffered Gel and Buffered Gel, or individual cards containing Anti-A (BIRMA-1 Clone), Anti-B (LB-2 Clone), or Anti-D (MS-201 Clone)].
- Reagent $A_1$ and B Cells,
  - 0.8%, ready for use in MTS™ ABO Reverse Grouping test
  - 3%, to be prepared as 0.8% for use in MTS™ ABO Reverse Group testing
- MTS™ Diluent 2 PLUS™ (a hypotonic buffered saline solution containing EDTA)
- ORTHO Confidence System, containing:
  - ORTHO Confidence Cell 1 – $A_1B$ rr (dce/dce) human red blood cells (pooled), 3% ± 1
  - ORTHO Confidence Cell 2 – O $R_1r$ (DCe/dce) human red blood cells (pooled), 3% ± 1
  - ORTHO Confidence Antibody – Dilute murine monoclonal anti-A and anti-B blended with human IgG anti-D (Anti-$Rh_o$) and anti-c (Anti-$hr^1$) containing bovine albumin, sodium chloride, sodium phosphate, EDTA, and 0.1% sodium azide as a preservative. The Rh-hr antibodies produce reactions at the antiglobulin phase, confirming the reactivity of reagent red blood cells for antibody detection and the Anti-IgG reagent. The reactivity of these antibodies with red blood cells suspended in MTS™ Diluent 2 serves to confirm this reagent as well. ORTHO Confidence Antibody may be diluted for quality control purposes to produce a 1-3+ reaction at the antiglobulin phase. Dilutions must be validated for use.

**Note:** In-house, non-commercial reagents and/or patient samples that are known to give the appropriate positive and negative test results may be substituted for the ORTHO Confidence System.

- Group AB Plasma known to lack unexpected antibodies

Do not use reagents beyond the expiration date.

Do not use gel cards that have not been shipped in an upright position.

Store gel cards upright at 2°C to 25°C.

Store diluent and red cells at 2°C to 8°C.

Bring reagents to room temperature (18°C to 25°C) prior to use.

A clear liquid layer should appear on top of the opaque gel in each microtube. Do not use gel cards if the gel matrix is absent or the liquid level in the microtube is at or below the top of the gel matrix. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts. Do not use cards if foil seals appear damaged or opened.

**Note:** Refer to ID-Micro Typing System™ Interpretation Guide for additional information related to the visual inspection of gel cards before use.

## Quality Control

The antibodies in the ORTHO Confidence System are intended to simulate normal blood samples and may be introduced into the normal laboratory workflow with patient and/or donor samples. The red blood cells and antibodies supplied with the ORTHO Confidence System should be tested following standard operating procedures in accordance with Instructions for Use accompanying each reagent used routinely. Perform an antibody detection test using ORTHO Confidence System or other appropriate blood group antibody and plasma known to lack unexpected antibodies. Perform ABO and D red blood cell typing using ORTHO Confidence Cell 1 and 2. Perform ABO Reverse Grouping test using ORTHO Confidence System and Group AB Plasma or other appropriate plasma samples that are known to give the appropriate positive and negative test results. Record results on the laboratory daily QC work sheet or ORTHO Confidence System Blood Bank Quality Control Record sheet.

## Procedure

### Antibody Detection QC Test Procedure

1. Visually inspect each gel card before use. Each microtube should have a clear liquid layer on top of opaque gel.

**CAUTION:** **Do not use gel cards if the gel matrix is absent or if the liquid level in the microtube is at or below the top of the gel matrix. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts. Do not centrifuge cards that have failed the visual inspection. The use of these cards may lead to erroneous test results. Do not use cards if foil seals appear damaged or opened.**

**Note:** Refer to ID-Micro Typing System™ Interpretation Guide for additional information related to the visual inspection of gel cards before use.

2. Label the MTS™ Anti-IgG Card with the appropriate identification.
3. Remove the foil seal from the gel card or from the individual microtubes used for testing.

**Note:** Foil should be removed immediately before testing or within one hour of testing. Once opened, the gel may begin to dry out which could affect test results. Ensure that residual foil does not block the opening of any microtube after removal of the foil.

4. Add 50 µL of the 0.8% reagents red blood cells to the appropriate microtube.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

5. Add 25 µL of the QC antibody to the appropriate microtube(s) as a positive control.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

6. Add 25 µL of the MTS 2 Diluent with no unexpected antibodies to the appropriate microtube(s) as a negative control.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

7. Incubate the Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Card for 15 minutes at 37± 2°C.
8. After incubation, centrifuge the gel card in the MTS™ Centrifuge at the preset conditions.
9. For manual readings, observe the front and the back of each microtube macroscopically and record reactions as described in the interpretation section of the corresponding MTS™ Gel Card package insert.

   When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

### ABO and D Red Blood Cell QC Test Procedure

**Preparation of a 4% suspension of red blood cells, for Anti-A, Anti-B, and Anti-D red blood cell testing**
**For 6-8 tests, from 3% cells**

**Note:** Alternative proportional volumes may be used. Packed cells or whole blood may also be used. Consult the package insert for the corresponding gel card.

1. Label two test tubes for ORTHO Confidence Cells 1 and 2, including lot number, date, time of preparation.
2. With an appropriate pipette, dispense 200 µL of each red blood cell sample to the appropriately labeled tube and centrifuge to pack the red blood cells.

3. Decant to a dry-cell button and add 150 µL of MTS™ Diluent 2 PLUS.

**ABO and D Red Blood Cell QC Test Procedure**

1. Label two MTS™ A/B/D Monoclonal and Reverse Grouping Cards: ORTHO Confidence Cell 1 and Confidence Cell 2. Label the Buffered Gel microtubes for $A_1$ and B cells, respectively.
2. Visually inspect each gel card before use. Each microtube should have a clear liquid layer on top of the opaque gel.

**CAUTION:** **Do not use gel cards if the gel matrix is absent or if the liquid level in the microtube is at or below the top of the gel matrix. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts. Do not use cards if foil seals appear damaged or opened.**

3. Remove the foil seal from the gel card.

**Note:** Foil should be removed immediately before testing or within one hour of testing. Once opened, the gel may begin to dry out which could affect test results.

4. Add 50 µL of the 0.8% suspensions of reagent $A_1$ and B red blood cells to the labeled Buffered Gel microtubes.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

5. Add 50 µL of QC antibody to the Buffered Gel microtubes of the Confidence Cell 2 MTS™ A/B/D Monoclonal and Reverse Grouping Card.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

6. Add 50 µL of the Group AB plasma to the Buffered Gel microtubes of the Confidence Cell 1 MTS™ A/B/D Monoclonal and Reverse Grouping Card.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

7. Add 10-12.5 µL of 4% ±1% ORTHO Confidence Cell 1, diluted in MTS™ Diluent 2 PLUS, to the Anti-A/-B/-D and Control microtubes of the labeled card.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

8. Add 10-12.5 µL of 4% ±1% ORTHO Confidence Cell 2, diluted in MTS™ Diluent 2 PLUS, to the Anti-A/-B/-D and Control microtubes of its labeled card.

**CAUTION:** **The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.**

9. Centrifuge the gel card in the MTS™ Centrifuge at the preset conditions.
10. For manual readings, observe the front and the back of each microtube macroscopically and record reactions as described in the interpretation section of the MTS™ Gel Card package insert.

    When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

## Interpretation of Results for ABO and D Red Blood Cell QC Test Procedure and for Antibody Detection QC Test Procedure (Refer to the Instructions for Use and the ID-Micro Typing System™ Interpretation Guide for detailed interpretation information)

| Expected Results | Anti-A | Anti-B | Anti-D | Control | A1 Cells | B Cells | Screening Cells (1 Cells, 2 Cells, 3 Cells) |
|---|---|---|---|---|---|---|---|
| Confidence Cell 1 | 1+- 4+ | 1+- 4+ | 0 | 0 | NT | NT | NT |
| Confidence Cell 2 | 0 | 0 | 1+- 4+ | 0 | NT | NT | NT |
| Confidence Antibody | NT | NT | NT | NT | 1+- 4+ | 1+- 4+ | 1+-4+ |
| MTS2 | NT | NT | NT | NT | NT | NT | 0 |
| MTS2P | NT | NT | NT | NT | 0 | 0 | NT |

NT = Not tested

**Note:** Some facilities consider negative test results in actual testing as adequate negative controls for the reagents. The manufacturer's recommendation is to include known positive and negative samples on each day of reagent use.

## Comments

If expected test results are observed, procedures are being performed accurately, and reagents and equipment are performing properly. If unexpected results are observed, the problem may be due to improper test performance, faulty equipment, reagent contamination or deterioration. The source of the problem should be determined before test results are reported.

Since commercially prepared blood grouping reagents and reagent red blood cells must meet FDA specificity requirements, extensive daily specificity testing by blood bank laboratories is redundant. The essential property to be confirmed by each laboratory is reagent reactivity.

## Limitations of the Procedure (Refer to the Instructions for Use and the ID-Micro Typing System™ Interpretation Guide for detailed product limitations)

- Individual laboratory procedures may affect the final reaction strength observed in tests performed with ORTHO Confidence Antibody.

## References

1. Package insert: ORTHO® Confidence Antibody, Current revision. Raritan, NJ: Ortho-Clinical Diagnostics, Inc.
2. Roback, J. (ed) Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008
3. Instructions for Use: Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Card (J32848), current revision. Pompano Beach, FL: Micro Typing Systems, Inc.
4. Instructions for Use: MTS™ A/B/D Monoclonal and Reverse Grouping Card (J32851)™, Current revision. Pompano Beach, FL: Micro Typing Systems, Inc.
5. Instructions for Use: MTS™ Diluent 2™ Red Blood Cell Diluent, Current revision. Pompano Beach, FL: Micro Typing Systems, Inc.
6. Instructions for Use: MTS™ Diluent 2 PLUS™ Red Blood Cell Diluent, Current revision. Pompano Beach, FL: Micro Typing Systems, Inc.
7. Package insert: Reagent Red Blood Cells 0.8% SELECTOGEN®, Current revision. Raritan, NJ: Ortho-Clinical Diagnostics, Inc.
8. Package insert: Reagent Red Blood Cells 0.8% SURGISCREEN®, Current revision. Raritan, NJ: Ortho-Clinical Diagnostics, Inc.
9. Package insert: Reagent Red Blood Cells ORTHO® 0.8% Pooled Screening Cells, Current revision. Raritan, NJ: Ortho-Clinical Diagnostics, Inc.
10. Package insert: Reagent Red Blood Cells 0.8% AFFIRMAGEN®, Current revision. Raritan, NJ: Ortho-Clinical Diagnostics, Inc.

# PROCEDURE 15

# QC

**Quality Control of MTS™ Manual Gel Test System Reagents**

## Authorization

Supervisor: _____ Date Instituted: 6/5/15

Pathologist: See cover Sheet Date Reviewed: _____

**Note:** It may be necessary, and is acceptable, to modify any or all of these procedures to meet individual facility requirements. A facility may choose to use only those procedures it deems appropriate; however, consideration must be given to the particular product in use and its package insert, reference manual and user's guide prior to altering any portion of this information. It is the responsibility of the end user to ensure that the procedures, as they are currently written or modified by the end user to meet needs, comply with regulations of local, state and federal agencies and that appropriate documentation is available upon request to demonstrate changes to original documents and effective dates when changes were implemented.

## Revision History

| Date of Revision | Version | Description of Technical Changes |
|---|---|---|
| 2013-11-15 | 5.1 | • Removed incubator and centrifuge specifications from MTS™ Centrifuge: Periodic Checks Quality Control Record and MTS™ Incubator and MTS™ Centrifuge: Daily Checks Quality Control Record. Added instruction to refer to instrument manuals for acceptable values. |
| 2010-05-31 | 5.0 | • Aligned content with Instructions for Use: MTS™ A/B/D Monoclonal and Reverse Grouping Card (J32851), Anti-Human Globulin Anti-IgG (Rabbit) MTS™ Anti-IgG Card (J32848).<br>• Updated product references and trademarks.<br>• Added references to ID-Micro Typing System™ Interpretation Guide<br>• Expanded limitations of the procedure to include guidance for resolving rouleaux test interference in agreement with Instructions for Use.<br>• Added caution against the pre-centrifugation of cards that have failed visual inspection.<br>• Replaced "package insert" with "Instructions for Use".<br>• Updated References section. |
| 2005-05-02 | 4.0 | • Added **Manual** to the name of the procedure.<br>• Changed the name to **ORTHO Confidence Antibody** and **Cell 1** and **Cell 2**.<br>• Changed format of document, added change bars to specific changes, and changed the date format to YYYY-MM-DD.<br>• Used the term **red blood cells** consistently.<br>• In the Principle section, added the last paragraph.<br>• In the Reagents section, changed the test to ABO Reverse Grouping test.<br>• In the Quality Control section,<br>– Changed the name of the document to Instructions for Use.<br>– Added **red blood cells** to the 4th sentence and reworded the 5th sentence in the paragraph.<br>• In the Procedure section,<br>– Deleted the Note explaining the proper 0.8% red blood cell concentration.<br>– Added step 1 to visually inspect gel cards and the Caution statement.<br>– Added **or within one hour of testing** to the Notes regarding opening the foil of the gel card.<br>– Added the sentence **Erroneous results due to carryover may occur** to the Caution stating the pipette tip not touching the gel card.<br>– In the Antibody Detection QC Test Procedure, reworded steps 4, 5, and 6.<br>– Included the Caution about the pipette tip not touching the gel card after steps 4, 5, and 6 in the Antibody Detection QC Test Procedure and after steps 4, 5, 6, 7, and 8 in the ABO and D Red Blood Cell QC Test Procedure.<br>– Added **Test Procedure** to the title ABO and D Red Blood Cell QC.<br>– In ABO and D Red Blood Cell QC Test Procedure, Preparation of a 4% suspension section, changed the number of tests to 6-8, added the alternative whole blood, and changed the volume to 200 µL in step 2 and 150 µL in step 3.<br>– Deleted the Note explaining how the formula was developed.<br>– In the ABO and D Red Blood Cell QC Test Procedure, added the last sentence to step 1, the Confidence Cell 2 in step 5, and the Confidence Cell 1 in step 6.<br>• In the Interpretation of Results table, changed the name of the table, changed values to 1+-4+ for Anti-A, Anti-B, Anti-D, A1 Cells, and B Cells in the first three rows, and changed the values to NT for Anti-A, Anti-B, Anti-D, and Control columns for the last row.<br>• In References, used **Current revision** for all the references to Package inserts and changed reference 2 to the 2002 edition of the Technical Manual.<br>• Added this Revision History.<br>• Edited or added charts on pages 7 through 20. |