PROCEDURE
Corewell Health East - ORTHO VISION Analyzer QC - 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 provides the Blood Bank staff with stepwise directions and procedures to perform and assess quality control (QC) for testing on the ORTHO VISION™ Analyzer that has been validated and approved at each site.

The ORTHO VISION™ has been configured by an administrative user to require daily QC testing for ABO/Rh Type, Antibody Screen, and Gel DAT. QC Testing must be performed and recorded as acceptable prior to testing of patient or donor samples.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. Definitions

A. **MBC:** Method based control. Refers to a system control that uses a sample of whole blood or a manufactured substitute to perform quality control on the system.

B. **Daily**: 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.

C. **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

A. MTS™ A/B/D Monoclonal and Reverse Grouping Cards
B. MTS™ Anti-IgG Cards

Entities will reference associated Documentation contained within this document as applicable
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C. MTS™ A/B/D Monoclonal Grouping Cards
A. MTS™ Anti-C (Monoclonal) Card
B. MTS™ Anti-E (Monoclonal) Card
C. MTS™ Anti-c (Monoclonal) Card
D. MTS™ Anti-e (Monoclonal) Card
E. MTS™ Monoclonal Rh Phenotype Card
F. 0.8% AFFIRMAGEN® Reagent Red Blood Cells (reverse typing)
G. 0.8% SELECTOGEN® Reagent Red Blood Cells (antibody screen)
H. MTS™ Diluent 2 PLUS
I. MTS™ Diluent 2
J. ORTHO™ Daily QC Simulated Whole Blood Quality Control Kit
K. Gel DAT QC Samples
L. ORTHO VISION™ Evaporation Caps
M. Specimen centrifuge

5. Quality Control

A. **Profiles:**

1. **Daily QC (performed at all sites)** - may consist of Type testing, Antibody Screen testing, Gel DAT testing, and confirmatory testing of donor RBCs. The table below indicates the actual test that is ordered and performed on the ORTHO VISION™, the samples that will be used for QC, the expected results, the gel cards, and the Diluent required to perform the testing.

ORTHO VISION™ Test	Sample(s) Used for QC	Expected Results	Gel Cards Used	Diluent Used
TYPE	ORTHO Daily QC Vial 3	A Positive	MTS™ A/B/D Monoclonal and Reverse Grouping Cards	MTS™ Diluent 2 PLUS
TYPE	ORTHO Daily QC Vial 4	B Negative	MTS™ A/B/D Monoclonal and Reverse Grouping Cards	MTS™ Diluent 2 PLUS
ABSCG	ORTHO Daily QC Vial 4	Positive	MTS™ Anti-IgG Cards	None
ABSCG	ORTHO Daily QC Vial 1	Negative	MTS™ Anti-IgG Cards	None
DATGL	Positive Gel DAT Control	Positive	MTS™ Anti-IgG Cards	MTS™ Diluent 2
DATGL	Negative Gel DAT Control	Negative	MTS™ Anti-IgG Cards	MTS™ Diluent 2
RTDN	ORTHO Daily QC Vial 3	A Positive	MTS™ A/B/D Monoclonal Grouping Cards	MTS™ Diluent 2 PLUS
RTDN	ORTHO Daily QC Vial 4	B Negative	MTS™ A/B/D Monoclonal Grouping Cards	MTS™ Diluent 2 PLUS

2. **Day of Use Testing: Rh Antigen testing (Dearborn and Royal Oak only)**- may consist of E antigen testing, C antigen testing, c antigen testing, e, and/or Rh Phenotype testing. The table below indicates the actual test that is ordered and performed on the ORTHO VISION™, the samples that will be used for QC, the expected results, the gel cards, and the Diluent required to perform the testing.

ORTHO VISION™ Test	Sample(s) Used for QC	Expected Results	Gel Cards Used	Diluent Used
C	ORTHO Daily QC Vial 1	C Positive	MTS™ Anti-C (Monoclonal) Card	MTS Diluent 2 PLUS™
C	ORTHO Daily QC Vial 3	C Negative	MTS™ Anti-C (Monoclonal) Card	MTS Diluent 2 PLUS™
E	ORTHO Daily QC Vial 1	E Positive	MTS™ Anti-E (Monoclonal) Card	MTS Diluent 2 PLUS™
E	ORTHO Daily QC Vial 2	E Negative	MTS™ Anti-E (Monoclonal) Card	MTS Diluent 2 PLUS™
LC	ORTHO Daily QC Vial 1	c Positive	MTS™ Anti-c (Monoclonal) Card	MTS Diluent 2 PLUS™
LC	ORTHO Daily QC Vial 2	c Negative	MTS™ Anti-c (Monoclonal) Card	MTS Diluent 2 PLUS™
LE	ORTHO Daily QC Vial 1	e Positive	MTS™ Anti-e (Monoclonal) Card	MTS Diluent 2 PLUS™
LE	ORTHO Daily QC Vial 3	e Negative	MTS™ Anti-e (Monoclonal) Card	MTS Diluent 2 PLUS™
RHPH	ORTHO Daily QC Vial 1	C, E, c, e Positive	MTS™ Monoclonal Rh Phenotype Card	MTS Diluent 2 PLUS™
RHPH	ORTHO Daily QC Vial 2	E and c Negative	MTS™ Monoclonal Rh Phenotype Card	MTS Diluent 2 PLUS™
RHPH	ORTHO Daily QC Vial 3	C and e Negative	MTS™ Monoclonal Rh Phenotype Card	MTS Diluent 2 PLUS™

B. Reagents

1. Diluents: MTS Diluent 2 PLUS™ and MTS Diluent 2™

a. The diluents are stored at 2ºC – 8ºC.
b. When a new bottle is opened, the “open date” and the technologist’s initials shall be written on the bottle.
c. Do not use the diluent if there is any evidence of discoloration, turbidity or sign of contamination.
d. Diluents will be inspected and rotated daily.

2. **Test Cells: 0.8% AFFIRMAGEN® Reagent Red Blood Cells (reverse typing) and 0.8% SELECTOGEN® Reagent Red Blood Cells (antibody screen)**
   a. All reagent red blood cells must be properly suspended before being loaded on the analyzer by gently rolling/swirling the bottles.
   b. Avoid agitation which could cause bubbles in the fluids. Remove any bubbles from the surface of the fluids prior to loading on the analyzer.
   c. Be careful to maintain the concentration and integrity of the fluids.
   d. Reagent red blood cells have a 5-day on-board stability when the evaporation caps are used.
   e. When new bottles are opened, the "open date", new expiration date, if applicable (shorter of 5 days from the open date or the original expiration date), and the technologist's initials shall be written on the bottles.
   f. Test cells shall be stored at 2ºC – 8ºC and must be brought to room temperature before use.
   g. Do not use the reagent red cells if discoloration or visible signs of hemolysis are present.
   h. Reagents will be replaced according to their on-board stability.
   i. Ensure the reagent red cell bottles have evaporation caps affixed.
3. **Gel Cards used for QC Testing: MTS™ A/B/D Monoclonal and Reverse Grouping Cards, MTS™ Anti- IgG Cards, MTS™ A/B/D Monoclonal Grouping Cards, MTS™ Anti-C (Monoclonal) Card, MTS™ Anti-E (Monoclonal) Card, MTS™ Anti-c (Monoclonal) Card, MTS™ Anti-e (Monoclonal) Card, MTS™ Monoclonal Rh Phenotype Card**
   a. The gel cards used for QC testing are stored in an upright position.
   b. The following gel cards are stored at 2ºC - 25ºC:
      1) MTS™ A/B/D Monoclonal and Reverse Grouping Cards
      2) MTS™ Anti- IgG Cards
      3) MTS™ A/B/D Monoclonal Grouping Cards
   c. The following gel cards are stored at 1ºC - 8ºC:
      1) MTS™ Anti-C (Monoclonal) Card
      2) MTS™ Anti-E (Monoclonal) Card
      3) MTS™ Anti-c (Monoclonal) Card
      4) MTS™ Anti-e (Monoclonal) Card
      5) MTS™ Monoclonal Rh Phenotype Card
   d. Each well of the gel card must 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) Liquid has splashed into the upper portion of a well.
      5) Foil seals appear damaged or opened.

C. **Samples**
1. **Gel DAT QC Samples**
   a. Positive and negative gel DAT controls will be used for QC of gel DATs on the ORTHO VISION™.
   b. The gel DAT controls will be made as needed in the Corewell Health Department of Transfusion Medicine using RBC segments of Rh-positive donor units in combination with saline and Ortho BioClone® Anti-D reagent, as described in Transfusion Medicine procedure, Corewell Health East - Preparation of Positive and Negative Gel DAT QC Samples - All Beaumont Hospitals .
   c. The expiration date of the gel DAT controls is the shortest of the expiration dates out of the donor unit, normal saline, and Ortho BioClone® Anti-D Reagent.
   d. Prepared QC samples will be stored at 2ºC – 8ºC when not in use and are not required to be mixed before each use.
2. **ORTHO™ Daily QC Samples**

a. The ORTHO™ Daily QC samples are used for the QC of gel method for the ABO/Rh Type, Antibody Screen, the confirmatory testing of donor samples, MTS™ Rh Antigen Typing Cards.
b. The ORTHO™ Daily QC vials shall be stored at 2ºC – 8ºC.
c. Once opened, the ORTHO™ Daily 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.
d. Once the ORTHO™ Daily QC vials are centrifuged, they are stored in a rack in an upright position, to avoid having to centrifuge the vials each time before testing.

D. Instructions

1. Maintenance must be completed before performing the daily QC testing. Refer to Transfusion Medicine procedure Corewell Health East - ORTHO VISION Analyzer Maintenance - All Beaumont Hospitals . Any manual calibration or maintenance not covered is performed at a frequency determined by Ortho Clinical Diagnostics (OCD) and will only be performed by an authorized OCD Field Service Engineer, trained and certified to service the ORTHO VISION™.
2. QC for routine testing reagents will be tested each day and recorded as acceptable by initialing the box on attached *ORTHO VISION™ Analyzer Maintenance and QC Log*.
3. RTDN QC is only required on the ORTHO VISION™ if it is performing donor unit confirmatory testing. ORTHO VISION™ analyzers that do not run this test do not require the daily RTDN QC.
4. QC for antigen typing profiles should be performed on the ORTHO VISION™ when patient or donor unit antigen typing is to be performed on the ORTHO VISION™. Appropriate positive and negative controls for antigen typing profiles must be tested once per day of use in accordance with Transfusion Medicine procedures Corewell Health East - Quality Control of Blood Bank Reagents - All Beaumont Hospitals and Corewell Health East - Antigen Typing - Blood Bank - All Beaumont Hospitals .
5. The ORTHO VISION™ has a system enforced QC interval length.
   a. The system tracks the time that has elapsed since the last successful QC was performed.
   b. If the time since the last successful QC exceeds the set QC interval length time of 28 hours, the system will prevent processing of tests.
6. QC will always be run as a STAT.
7. QC testing shall be performed in advance of, but NOT in parallel with, sample testing.
8. All quality control results are reviewed by the instrument operator as soon as the results are available.
9. Any questionable or discrepant results must be resolved before the instrument may be used for patient or donor unit testing.
10. The technologist reviewing the ORTHO VISION™ QC is responsible for making sure all of the appropriate results were obtained. Repeat testing must be performed as indicated.
11. If QC results are edited for any reason, a comment must be added before saving the results to document why the edit was made.
12. For each new lot of QC, the QC samples must be registered into the specific profiles.
13. The system software performs all the routine calibration functions for the ORTHO VISION™.
14. Failing Quality Control:
    a. If the QC fails, then testing of patient and donor samples may not be initiated. QC testing must pass to initiate testing.
    b. QC failures shall be investigated before release of test results, products, or services.
    c. If the visual inspection is unsatisfactory or the QC fails upon repeat due to a specific reagent: do not use the applicable reagent, place it in quarantine, and document the occurrence in an internal variance.

E. **QC Screen / Action Buttons:** The QC main screen is the starting point for all quality control functions. Use this screen to review all controls established for the system and print QC reports (MBC).

1. QC Action Buttons:
   a. Show QC History: Displays the QC history of the selected profile, for up to 7 days from the current date.

   b. Show MBC Report: Displays information about the QC state and the most recent completed MBC QC job per QC sample set.

   c. Run QC Job: Starts a QC job.

6. Procedure

A. Running a QC Sample. Ensure all resources are loaded prior to running QC.
   1. Touch the QC menu button.

   2. Select the profile you wish to process and touch the Run QC Job action button.

   3. Verify the Lot # of QC material and reagents. Change QC material lot number if needed. Highlight lot number(s) of reagents and cards to be QC'd.
   4. Touch Save and Start. This saves the entries or changes made on the screen and starts the order.

   5. Repeat steps 2 and 3 for all profiles requiring QC.
      a. QC profile options: TYPE, ABSCG, DATGL, RTDN, E, C, LE, LC, RHPH.
   6. Touch the Samples menu button, then select a ring position into which you want to load the QC samples.

7. Touch Load/Unload and open the door.

8. Place the rack or racks in the Load Station and close the door.
   a. The system inventories the samples and begins running the QC.

B. **Changing QC (ORTHO™ Daily QC and Gel DAT) Lots**.

1. Touch the QC menu button.

2. Select the profile you wish to process and touch the Run QC Job action button.

3. To configure the QC material, touch Change OCD QC Sample ID.

4. Delete the existing ID and enter the new QC barcode using the hand-held barcode scanner. Touch save.

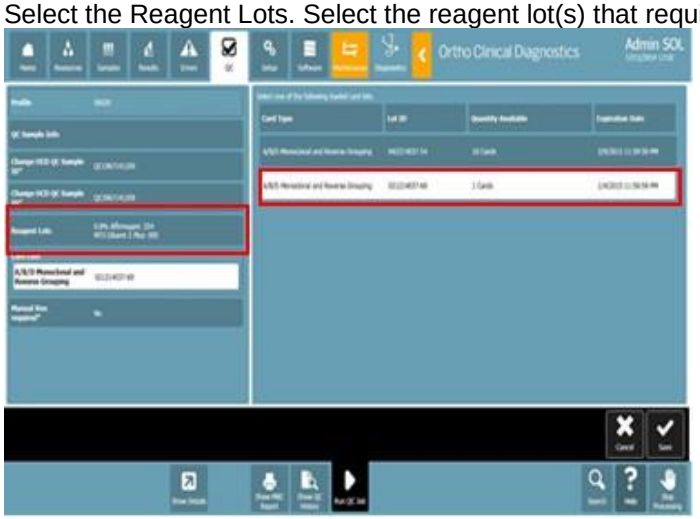
a. This will enter the QC material Lot# twice. If manually typing in the lot number information, type the barcode twice.
b. Make sure all applicable QC samples are changed to the new lot before saving.

5. Repeat steps 1-4 for each MBC Profile.
   a. TYPE, ABSCG, RTDN, E, C, LE, LC, and RHPH for ORTHO™ Daily QC samples.
   b. DATGL for Gel DAT samples.

C. QC of Different ID-MTS Gel Card or Reagent Red Cell Lots.

1. Load all resources including all lots requiring QC.
2. Touch the QC menu button then touch the MBC profile requiring QC.

3. Touch Run QC Job.
4. Select the Reagent Lots. Select the reagent lot(s) that require QC.



a. If there is more than one reagent lot loaded on the instrument, the default selection is the lot that was most recently registered. Touch twice to view all lot numbers that are loaded on the analyzer. To QC multiple lots, an additional request for QC testing on additional material is required.

Entities will reference associated Documentation contained within this document as applicable
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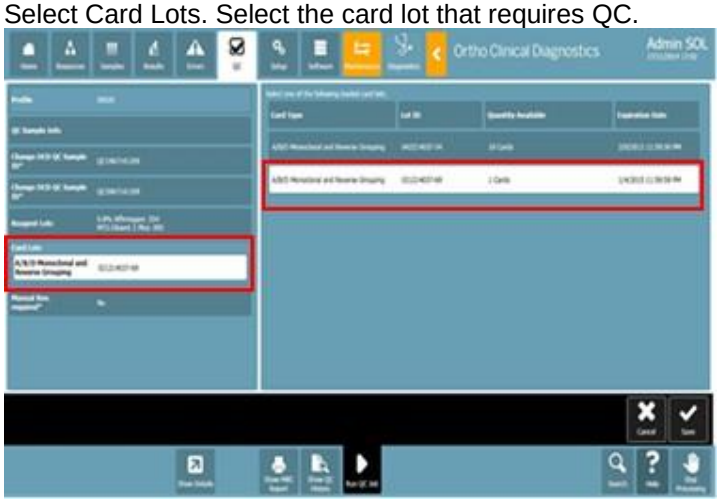
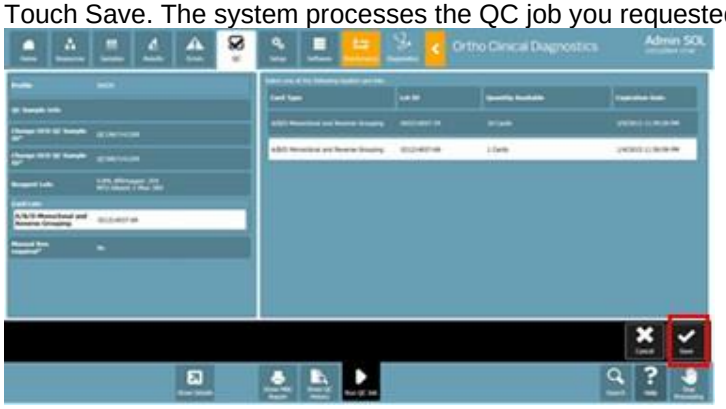
5. Select Card Lots. Select the card lot that requires QC.



a. If there is more than one required card lot loaded on the instrument, the default selection is the lot that was most recently registered. Touch the card type twice to view all lots that are loaded on the analyzer. To QC multiple lots, an additional request for QC testing on additional material is required.

6. Select Manual Rev. Required and touch No.

7. Touch Save. The system processes the QC job you requested.



D. Printing QC Results.

1. Touch the QC menu button.

2. Touch the desired MBC profile name.

a. TYPE, ABSCG, DATGL, RTDN, E, C, LE, LC, or RHPH.

3. Touch Show MBC Report.

4. Touch Print.

5. Return to Result Tab. Archive the QC results by selecting it and then touching Archive Order.

a. The result will no longer appear on the Results screen.

7. Results/Interpretation

A. Once the QC has been reviewed and accepted, print, initial, and date the printout and place it in the designated storage area.

B. Initial the *ORTHO VISION™ Analyzer Maintenance and QC Log in* the QC completed box. Technologist initials indicated that appropriate results for QC have been obtained

8. Revisions

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

9. References

1. AABB, Standards for Blood Banks and Transfusion Services, current edition.
2. College of American Pathologists, Transfusion Medicine Checklist, current edition.
3. Cohn, C.S., Delaney, M, Johnson, S.T., Katz, L.M. (2020)
4. Technical Manual.(19th ed.). AABB.
5. Ortho Clinical Diagnostics, Rochester, NY, Ortho Vision General Operator Training Manual, Publication J56102.
6. Ortho Clinical Diagnostics, Rochester, NY, Electronic Publication number J56102.
7. ORTHO VISION® Analyzer Electronic Library, Software version 5.3.0.0.
8. ORTHO VISION® Analyzer ID-MTS® Gel Cards Reference Guide (J40050).
9. ORTHO VISION® Analyzer ID-MTS Gel Cards Self-Service Customer Procedures Guide J40055ENNA.
10. ID-Micro Typing System® Implementation Guide 6902200.

10. Procedure Development and Approval

Document Owner:

Laura Judd (Operations Specialist)

Writer(s):

Melissa Bajcz (Medical Technologist Lead)

Reviewer(s):

Alyssa Malone (Medical Technologist Lead), Autumn Ryan (Medical Technologist Lead), Danae Regan (Medical Technologist Lead), Hilary Morey (Medical Technologist Lead), Karrie Torgerson (Medical Technologist Lead), Leila Baalbaki (Medical Technologist Lead), Susan Pelley (Medical Technologist Lead), Suzanne Chahine (Medical Technologist Lead)

Approver:

Ann Marie Blenc (System Med Dir, Hematopath), Ashley Beesley (Mgr, Laboratory), Brittnie Berger (Dir Sr, Lab Operations), Hassan Kanaan (OUWB Clinical Faculty), Jennifer Yaker (Mgr, Laboratory), Jeremy Powers (Chief, Pathology), John Pui (Chief, Pathology), Kelly Sartor (Mgr, Division Laboratory), Kristen DiCicco (Mgr, Laboratory), Kristin Russell (Mgr, Laboratory), Kristina Davis (Staff Physician), Masood Siddiqui (Staff Pathologist), Muhammad Arshad (Chief, Pathology), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Teresa Lovins (Supv, Laboratory)

11. Keywords

Not Set