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Applicability	All Beaumont Hospitals

ORTHO VISION Analyzer QC

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide the Blood Bank staff with stepwise directions and policies to perform and assess quality control (QC) on the ORTHO VISION™ Analyzer.

II. POLICY STATEMENT:

The ORTHO VISION™ has been configured by an administrative user to require daily QC testing. QC Testing must be performed and recorded as acceptable prior to testing of patient or donor samples.

III. QUALITY CONTROL PROFILES:

Daily QC may consist of Type & Screen testing, gel DAT testing, confirmatory testing of donor samples, and Rh(D) neonate 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, and the gel cards required to perform the testing.

ORTHO VISION™ Test	Sample(s) Used for QC	Expected Results	Gel Cards Used	Diluent Used
TS / CORDE	AlbaQ™ Vial 1	Type: A Negative ABSC: Positive	Type: MTS A/B/D Monoclonal and Reverse Grouping Cards™ ABSCG: MTS Anti-IgG Cards™	MTS Diluent 2 PLUS™
TS / CORDE	AlbaQ™ Vial 3	Type: B Positive	Type: MTS A/B/D Monoclonal and Reverse Grouping Cards™	MTS Diluent 2 PLUS™

		ABSC: Negative	ABSCG: MTS Anti-IgG Cards™	
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	AlbaQ™ Vial 1	A Negative	MTS A/B/D Monoclonal Grouping Cards™	MTS Diluent 2 PLUS™
RTDN	AlbaQ™ Vial 3	B Positive	MTS A/B/D Monoclonal Grouping Cards™	MTS Diluent 2 PLUS™
RTDP	AlbaQ™ Vial 2	Type: O	MTS A/B Monoclonal Grouping Cards™	MTS Diluent 2 PLUS™
RTDP	AlbaQ™ Vial 4	Type: A_2B	MTS A/B Monoclonal Grouping Cards™	MTS Diluent 2 PLUS™
NBRHR	AlbaQ™ Vial 3	Rh(D): Positive Control: Negative	Rh(D): MTS Anti-D Monoclonal IgM Cards™ Control: MTS Control Cards™	MTS Diluent 2 PLUS™
NBRHR	AlbaQ™ Vial 1	Rh(D): Negative Control: Negative	Rh(D): MTS Anti-D Monoclonal IgM Cards™ Control: MTS Control Cards™	MTS Diluent 2 PLUS™

IV. ACRONYMS:

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.

V. REAGENTS / SUPPLIES / EQUIPMENT:

A. MTS A/B/D Monoclonal and Reverse Grouping Cards™
B. MTS Anti-IgG Cards™
C. MTS A/B/D Monoclonal Grouping Cards™
D. MTS A/B Monoclonal Grouping Cards™
E. MTS Anti-D Monoclonal IgM Cards™
F. MTS Control Cards™
G. 0.8% AFFIRMAGEN® Reagent Red Blood Cells (reverse typing)
H. 0.8% SELECTOGEN® Reagent Red Blood Cells (antibody screen)
I. MTS Diluent 2 PLUS™
J. MTS Diluent 2™
K. AlbaQ-Chek™ QC Samples

L. Gel DAT QC Samples

M. ORTHO VISION™ Evaporation Caps

N. Specimen centrifuge

VI. INSTRUCTIONS:

A. Maintenance must be completed before performing the daily QC testing. Refer to ORTHO VISION™ Analyzer Maintenance. 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™.

B. QC shall be tested each day and recorded as acceptable by initialing the box on attached *ORTHO VISION™ Analyzer Maintenance and QC Log*.

C. NBRHR QC is only required on the ORTHO VISION™ if it is performing the neonate Rh(D) testing. ORTHO VISION™ analyzers that are not designated for running this test do not require the daily NBRHR QC.

D. RTDN and RTDP 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 and RTDP QC.

E. QC for antigen typing profiles are not currently performed on the ORTHO VISION™. Appropriate positive and negative controls for antigen typing profiles must be tested once per day of use using manual methods in accordance with QC and Blood Bank antigen typing procedures.

F. The ORTHO VISION™ has a system enforced QC interval length.

    1. The system tracks the time that has elapsed since the last successful QC was performed.
    2. 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.

G. QC will always be run as a STAT.

H. QC testing shall be performed in advance of, but NOT in parallel with, sample testing.

I. All quality control results are reviewed by the instrument operator as soon as the results are available.

J. Any questionable or discrepant results must be resolved before the instrument may be used for patient or donor unit testing.

K. 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.

L. If QC results are edited for any reason, a comment must be added before saving the results to document why the edit was made.

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

N. Initial *ORTHO VISION™ Analyzer Maintenance and QC Log,* in the QC completed box.

Technologist initials indicated that appropriate results for QC have been obtained.

O. For each new lot of QC, the QC samples have to be registered into specific profiles.

P. The system software performs all of the routine calibration functions for the ORTHO VISION™.

Q. **Failing Quality Control:**

1. If the QC fails then testing of patient and donor samples may not be initiated. QC testing must pass in order to initiate testing.
2. QC failures shall be investigated before release of test results, products, or services.
3. 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.

VII. QUALITY CONTROL REAGENTS:

A. **Diluents: MTS Diluent 2 PLUS™ and MTS Diluent 2™**

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

B. **Test Cells: 0.8% AFFIRMAGEN® Reagent Red Blood Cells (reverse typing) and 0.8% SELECTOGEN® Reagent Red Blood Cells (antibody screen)**

1. All reagent red blood cells must be properly suspended before being loaded on the analyzer by gently rolling/swirling the bottles.
2. Avoid agitation which could cause bubbles in the fluids. Remove any bubbles from the surface of the fluids prior to processing.
3. Be careful to maintain the concentration and integrity of the fluids.
4. Reagent red blood cells have a 5 day on-board stability when the evaporation caps are used.
5. Test cells shall be stored at 2ºC – 8ºC and must be brought to room temperature before use.
6. Do not use the reagent red cells if discoloration or visible signs of hemolysis are present.
7. Reagents will be rotated according to their on-board stability.
8. Ensure the reagent red cell bottles have evaporation caps affixed.

C. **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 A/B Monoclonal Grouping Cards™, MTS Anti-D Monoclonal IgM Cards™, and MTS Control Cards™**

1. The gel cards used for QC testing are stored in an upright position at 2ºC - 25ºC.

2. Each well of the gel card must have a clear liquid layer on top of the opaque gel. 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. Liquid has splashed into the upper portion of a well.
    e. Foil seals appear damaged or opened.

VIII. QUALITY CONTROL SAMPLES:

A. **Gel DAT QC Samples.**
    1. Positive and negative gel DAT controls will be used for QC of gel DATs on the ORTHO VISION™.
    2. The gel DAT controls will be made as needed in the Beaumont 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 policy, Preparation of Positive and Negative Gel DAT QC Samples.
    3. The expiration date of the gel DAT controls is the **shorter** of the expiration date out of the donor unit, normal saline, and Ortho BioClone® Anti-D Reagent.
    4. Prepared QC samples will be stored at 2ºC – 8ºC when not in use, and are not required to be mixed before each use.

B. **AlbaQ-Chek™ QC Samples.**
    1. The AlbaQ-Chek™ samples are used for the QC of the Type & Screens, neonate Rh(D) testing, and the confirmatory testing of donor samples.
    2. The AlbaQ-Chek™Kit vials shall be stored at 2ºC – 8ºC.
    3. Once opened, the AlbaQ™ vials expire on the **shorter** of 7 days from the open date or the original expiration date. When opened, the “open date” and the technologist’s initials shall be written on the vials, as well as the new expiration date.
    4. Once the AlbaQ™ vials are spun down, they are stored in a rack in an upright position, to avoid having to re-centrifuge the vials each time before testing.

IX. 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).

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

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

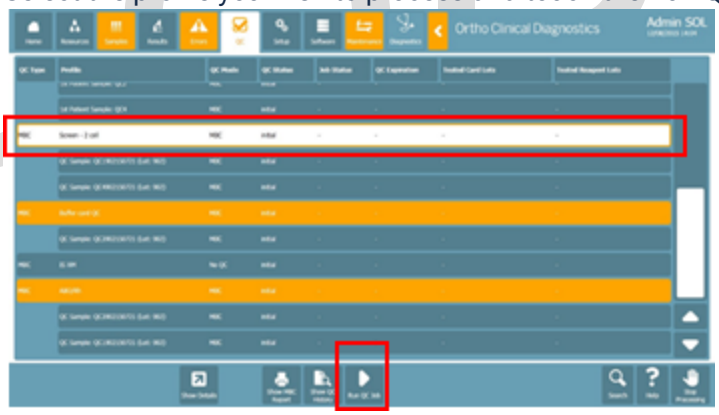
3. Run QC Job: Starts a QC job.

X. PROCEDURE:

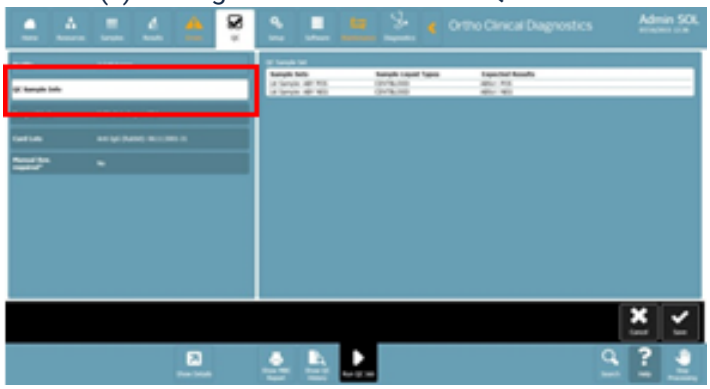
A. **Running a QC Sample.** Ensure all resources are loaded prior to running QC.

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 and reagents. Change QC 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 profiles: TS, DATGL, RTDN, RTDP, NBRHR.
6. Touch the Samples menu button, then select a ring position into which you want to load the QC samples.

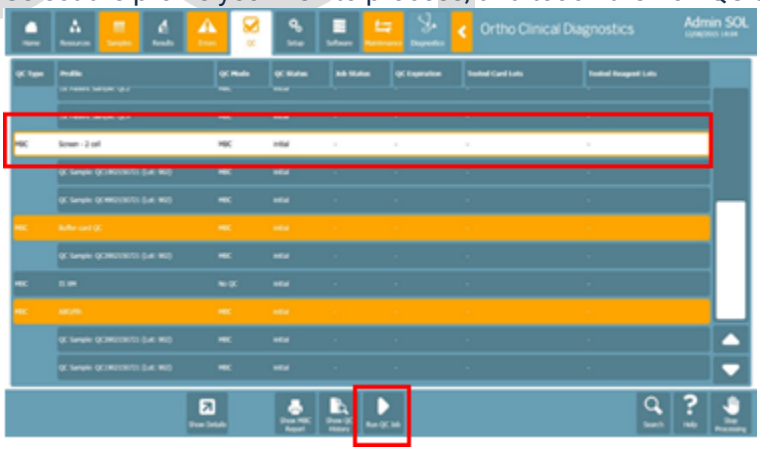
7. Touch Load/Unload and open the door.

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.

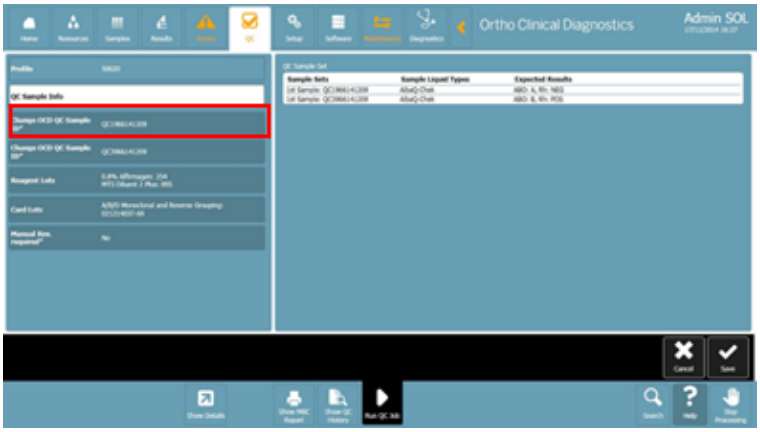
B. **Changing QC (AlbaQ-Chek™ and Gel DAT) Lots.**

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, touch Change OCD QC Sample ID.



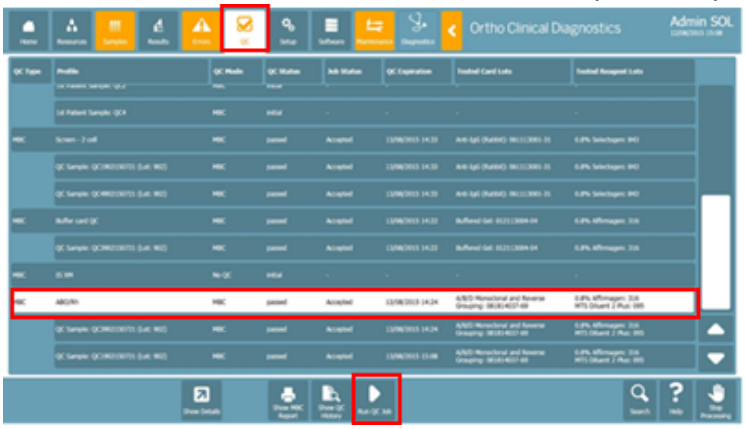
4. Delete the existing ID and enter the new QC barcode using the hand-held barcode scanner. Touch Save.

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

5. Repeat steps 1-4 for each MBC Profile.
   a. TS, RTDN, RTDP, and NBRHR for AlbaQ-Check™ samples.
   b. DATGL for Gel DAT samples.

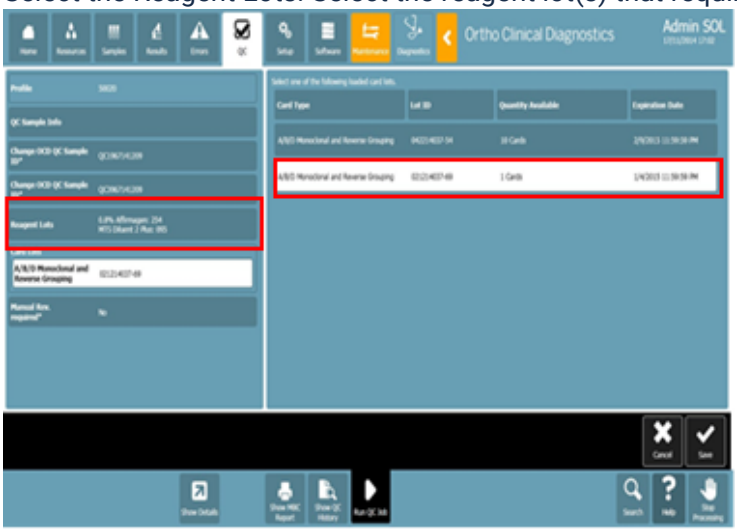
C. **QC of Different ID-MTS Gel Card or Reagent Red Cell Lots.**

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



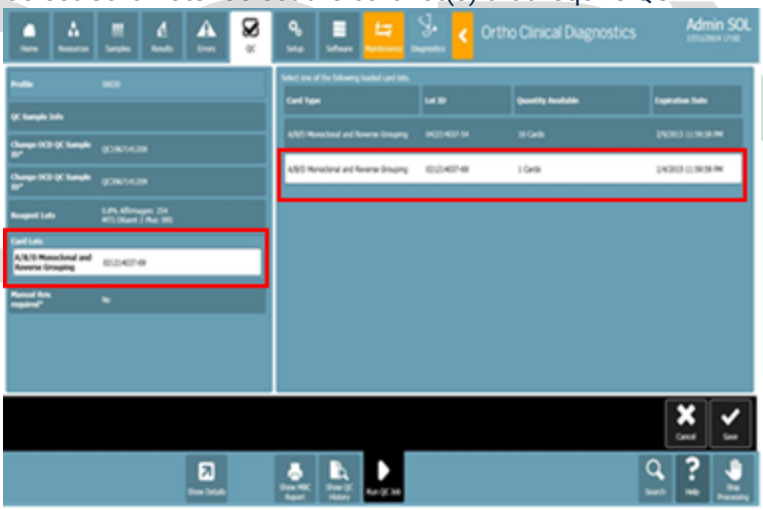
3. Touch Run QC Job.

4. Select the Reagent Lots. Select the reagent lot(s) that require QC.



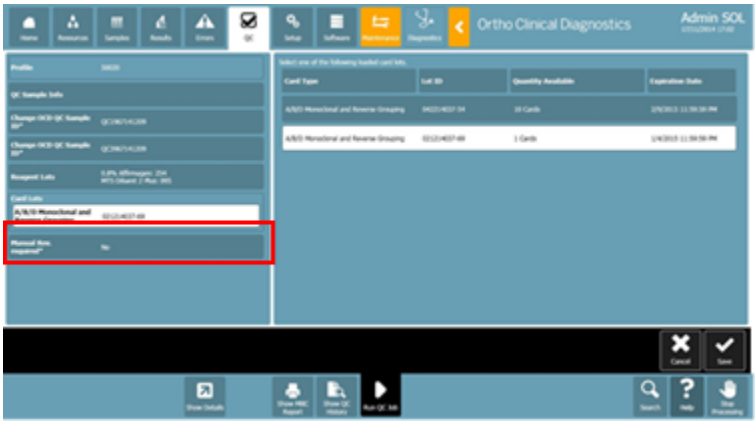
   a. If there is more than one reagent lot loaded on the instrument, the default selection is the lot that was most recently registered. Touch twice to view all lot numbers that are loaded on the analyzer.

5. Select Card Lots. Select the card lot(s) that require 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.

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. TS, DATGL, RTDN, RTDP, or NBRHR.
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.

XI. REFERENCES:

A. AABB, *Standards for Blood Banks and Transfusion Services,* current edition.

B. College of American Pathologists, *Transfusion Medicine Checklist,* current edition.

C. Cohn, C.S., Delaney, M, Johnson, S.T., Katz, L.M. (2020) *Technical Manual*.(19th ed.). AABB.

D. Ortho Clinical Diagnostics, Rochester, NY, Ortho Vision General Operator Training Manual, Publication J56102.

E. Ortho Clinical Diagnostics, Rochester, NY, Electronic Publication number J56102.

F. ORTHO VISION® Analyzer Electronic Library, Software version 5.3.0.0.

G. ORTHO VISION® Analyzer ID-MTS® Gel Cards Reference Guide (J40050).

H. ORTHO VISION® Analyzer ID-MTS Gel Cards Self-Service Customer Procedures Guide J40055ENNA.

I. ID-Micro Typing System® Implementation Guide 6902200.

Attachments

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ORTHO VISION Analyzer Maintenance and QC Log (03/01/2021)

Approval Signatures

Step Description	Approver	Date
	Kristina Davis: Staff Physician	4/24/2023
	Ann Marie Blenc: System Med Dir, Hematopath	3/17/2023
	Vaishali Pansare: Chief, Pathology	3/6/2023
	Ryan Johnson: OUWB Clinical Faculty	3/2/2023
	Muhammad Arshad: Physician	3/1/2023
	John Pui: Chief, Pathology	3/1/2023
	Jeremy Powers: Chief, Pathology	3/1/2023

Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	3/1/2023
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	3/1/2023
	Fatima Bazzi: Medical Technologist Lead	2/28/2023
	Abigail Swaney: Medical Technologist Lead	2/25/2023
	Kristen Lafond: Mgr Laboratory	2/16/2023
	Ashley Beesley: Mgr Laboratory	2/16/2023
	Katherine Persinger: Mgr Laboratory	2/16/2023
	Kelly Sartor: Supv, Laboratory	2/15/2023
	Rebecca Thompson: Medical Technologist Lead	2/15/2023
	Teresa Lovins: Supv, Laboratory	2/15/2023
	Michele Ferla: Medical Technologist Lead	2/15/2023
	Hilary Morey: Medical Technologist Lead	2/15/2023
	Karrie Torgerson: Supv, Laboratory	2/15/2023
	Brooke Klapatch: Medical Technologist Lead	2/15/2023
	Kelly Sartor: Supv, Laboratory	2/14/2023