1.0 Purpose

This document provides instruction for reagent, diluent and gel card quality control testing on the ORTHO VISION® Analyzer. The QC screen allows you to manage all quality control jobs and QC status information. Touch the QC button to access this screen.

1.1 Daily Quality Control

Quality Control will consist of four vials of Alba**Q**-**C**hek commercially prepared whole blood samples and one in-house prepared sample to verify DAT positive reactivity. The commercial QC samples are prepared with the intent of providing a ABORh interpretation, as well as examples of negative and positive reactions for all routine blood bank tests as well as donor unit confirmation typing. Refer to Table 1. Daily QC Test Performance.

- All required preventive maintenance must be successfully completed before perform QC.
- Alba**Q**-**C**hek commercially prepared whole blood controls from Alba Bioscience will be the default QC material.
- Samples for quality control may be manually prepared from donor units if commercial controls within a box set are exhausted early.
- Patients may be run with the controls, but results cannot be verified until the QC results pertaining to the tests are successful and accepted by the performing CLS.
- The Vision has a hard stop and will not allow any specimens to be tested if QC for that test fails.

Table 1. Vision Daily Quality Control

MBC PROFILE	Gel Cards	Card Number	Reagents
ABORh	ABD Reverse cards (2 cards)	037	MTS Diluent 2 Plus 0.8% Affirmagen
ABSC	IgG cards (2 ½ cards)	001	0.8% Surgiscreen
DAT IgG	IgG card (2 gel columns)	001	MTS Diluent 2
Buffer Card QC	Buffer card (2 gel columns)	004	None
O Pos Unit Type	A,B card (2 gel columns)	038	MTS Diluent 2 Plus
Rh Pos Unit Type	A/B card (4 gel colums)	057	MTS Diluent 2 Plus
Rh Neg Unit Type	ABD card (1 card or 6 gel colums)	053	MTS Diluent 2 Plus

Table 2. Alba**Q-C**hek® **Test Set-up and Expected Results for Daily QC**

QC Sample	Profile (Expected Results)	Profile (Expected Results)	Profile (Expected Results)	Profile (Expected Results)	Profile (Expected Results)	Profile (Expected Results)	Profile (Expected Results)
AlbaQ QC1 A Neg Anti-B Anti-D (rr)	ABORh (A Neg)	ABSC (Sc1 & Sc2 Positive)	Rh Neg Unit Type (A Neg)	Rh Pos Unit Type (A)	O Pos Unit Type (Anti-A,B = Pos)	Buffer Card QC (Reverse group A)	
AlbaQ QC2 O Pos Anti-A Anti-B Anti-c (R1R1)		ABSC (Sc2 & Sc3 Positive)			O Pos Unit Type (Anti-A,B = Neg)		
AlbaQ QC3 B Pos Anti-A	ABORh (B Pos)	ABSC (Negative)	Rh Neg Unit Type (B Pos)	Rh Pos Unit Type (B)			
AlbaQ QC4 AB Pos *DAT Neg							DAT IgG (DAT Pos)
Custom QC5 (3mL AlbaQ QC4 sample with 3 drops Anti-D) *DAT Pos							DAT IgG (DAT Neg)

*Screen cell positive reaction patterns may vary with QC lot.

1.2	**Rh Phenotype Quality Control (As Needed)** Rh Phenotype QC will be performed on day of use (when patient Rh Phenotype is performed on the Vision). Document the following in the Antigen Typing QC Binder: Rh Phen QC result and acceptability, Rh Phen card lot# and expiration date, and review. Rh Phen QC can be programmed and run simultaneously with patient sample if the Rh Phen card is not a new lot#. However, the CLS must verify and document that QC is acceptable before patient result can be reported.

Rh Phen QC

QC Specimen Name	QC Material	Gel Cards	Card Number	Tests	Reagent	Expected results
R1R1 (label a 10mmX75mm test tube with R1R1 barcode)	500uL 3% Surgiscreen® Cell 1	Rh Phen	048	Rh Phen	MTS Diluent 2 Plus	R1R1 (DCeDCe)
R2R2 (label a 10mmX75mm test tube with R2R2 barcode)	500uL 3% Surgiscreen® Cell 2	Rh Phen	048	Rh Phen	MTS Diluent 2 Plus	R2R2 (DcEDcE)

NOTE: 500uL is approximately 1cm from the bottom of a 10mmX75mm (skinny) test tube.

2.0 Scope

	Blood Bank CLS trained and competent in Vision QC performance.

3.0 Safety Precautions

a.	Use of PPE and current biological hazard safety practices will be followed as defined in the laboratory safety manual.
b.	If accessing the testing area long hair should be pulled back to avoid being caught by internal moving components.
c.	Handle all equipment with care. Mechanical parts may have sharp edges, pinch points, and corners that potentially could cause injury.

4.0 Equipment Calibration and Maintenance

a.	Daily PM performed successfully prior to QC testing.
b.	Weekly and Monthly PM when required are performed successfully prior to QC testing.

5.0 Supplies

Materials	Storage requirements	User requirements	Comments
MTS® A/B/D Monoclonal and Reverse Grouping Card	2-25°C	Room temperature	Store in an upright position
MTS A/B/D Monoclonal Grouping Card	2-25°C	Room temperature	Rh Neg Unit Type
MTS A/B Monoclonal Grouping Card	2-25°C	Room temperature	Rh Pos Unit Type
MTS Anti-A,B Murine Monoclonal Blend Card*	2-25°C	Room temperature	O Pos Unit Type
MTS Monoclonal Rh Phenotype Card*	2-25°C	Room temperature	D/C/E/c/e/ctrl Requires 4% ± 1% patient/donor cell suspension
MTS® Anti-IgG Card	2-25°C	Room temperature	DAT IgG Store in an upright position
MTS® Diluent 2	2-8°C	Room temperature	Used for DAT, XM and AC testing. Diluent should not be left on the instrument longer than 24 hours.
MTS® Diluent 2 Plus	2-8°C	Room temperature	Used for red cell typing. Diluents should not be left on the instrument longer than 24 hours.
0.8% AFFIRMAGEN® Reagent Red Blood Cells	2-8°C	Room temperature	Reagent red cells should not be left on the instrument longer than 5 days. Ensure reagent red cells are properly re-suspended prior to use.
0.8% SURGISCREEN® Reagent Red Blood Cells	2-8°C	Room temperature	
3% SURGISCREEN® Reagent Red Blood Cells	2-8°C	Room temperature	Sc1 (R1R1) and Sc2 (R2R2) used as QC samples for Rh Rhen.
AlbaQ-Chek Vials 1 - 4	2-8°C	Room temperature	Verify samples are labeled appropriately with manufacturer barcode or custom barcode. Samples may be used for 7 days from opening date.

6.0 Quality Control Samples

a.	Alba**Q-C**hek®, simulated whole blood QC is commercially prepared from red blood cells collected from blood donors. Each individual donation contains the appropriate ABO and RhD blood group antigens and also the appropriate ABO blood group antibodies. ABO and anti-D antibodies are of monoclonal origin and anti-c is of polyclonal origin. The concentration of red blood cells in each of the controls is 15% ± 2%. The red blood cells are suspended in a preservative solution to retard hemolysis and bacterial contamination. Refer to Alba Bioscience package insert. Vial 1 - Group A RhD Negative (rr) containing anti-B, anti-D. Vial 2 - Group O RhD Positive (R1R1) containing anti-A, anti-B, anti-c. Vial 3 - Group B RhD Positive (R1r) containing anti-A. Vial 4 - Group A_2B RhD positive.
b.	Customer prepared QC5 for positive DAT IgG daily QC.

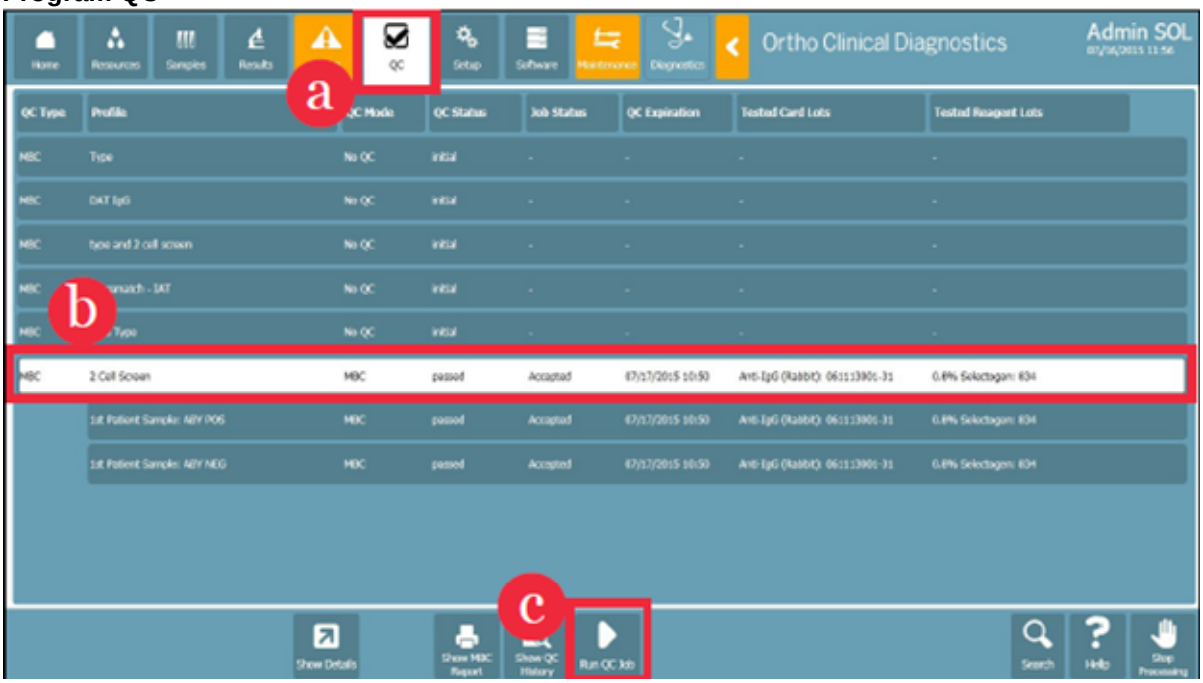
7.0 New Reagent Lot Confirmation of Acceptability

Step	Action
1.	Before a new lot of reagent/gel card is placed in use, the expected reactivity must be checked against the old reagent/gel card lot.
2.	If the same lot of Alba**Q-C**hek® was used to test the old reagent/gel card lot, the new reagent/gel card lot is acceptable if the reactivity is the same or within +/- 1 of the old lot.
3.	If a new lot of Alba**Q-C**hek® is started concurrently with a new reagent/gel card lot, the new reagent/gel card lot must be tested concurrently with the old reagent/gel card lot using the new lot of Alba**Q-C**hek® samples.
4.	The new reagent/gel card lot is acceptable if the reactivity is the same or within +/- 1 of the old lot.

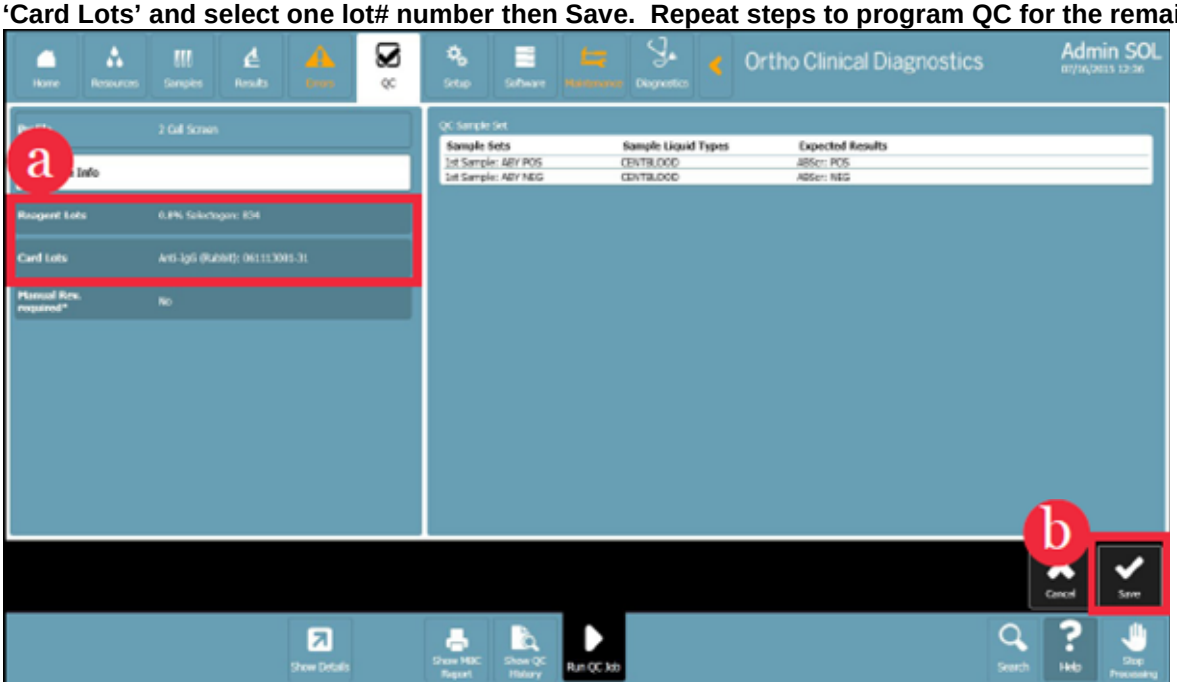
8.0 Procedure

Step	Action
1.	**Prepare QC 5** Prepare QC5 DAT positive sample by placing 3mL of well mixed sample from Alba**Q-C**hek® Vial 4 into a 12x75 mm test tube, add 3 drops of anti-D, mix and allow 15 minutes of incubation at room temperature before use. Label with "DAT POS" barcode label and mix well prior to QC testing. • Alternatively, empty 4 segments from O positive blood units into a 12x75 mm test tube, add 3 drops of anti-D, mix and let sit 15 minutes before use. Label with "DAT POS" barcode and mix before QC testing. **Prepare AlbaQ-Chek® controls** if opening a new boxed set. • Centrifuge all vials and QC5 prior to their first use. • Place a custom "DAT NEG" barcode on QC4. • Remove the color coordinated vial tops before each use. • Store upright in a specimen rack after each use. • Once opened the set is good for a maximum of 7 days and only needs to be centrifuged the first time. If one level runs out, replace the entire set.
2.	**Running QC** 1. Prior to running QC, load Resources that are needed for all the QC tests. 2. Touch the QC menu button. 3. Re-sort the profiles on your screen to bring the most recently run MBC controls to the top. a. Press QC Mode once to bring MBC to the top. b. Press QC expiration twice to bring the most recently run MBC to the top. 4. Select the profile you wish to process and touch the Run QC Job action button. 5. Touch Save. 6. There are 7 profiles to program daily: a. ABORh b. ABSC c. DAT IgG d. Buffer Card QC e. O POS unit typing f. Rh POS unit typing g. Rh NEG unit typing 7. Repeat steps for all profiles requiring QC.
3.	**Load QC samples** 1. Touch **Samples >** then select a ring position into which you want to load samples. 2. Touch **Load/Unload** and open the door. 3. Select any additional ring positions into which you want to load QC samples. 4. Place the rack or racks in the Load Station and close the door. • Result: The system inventories and posts the samples.

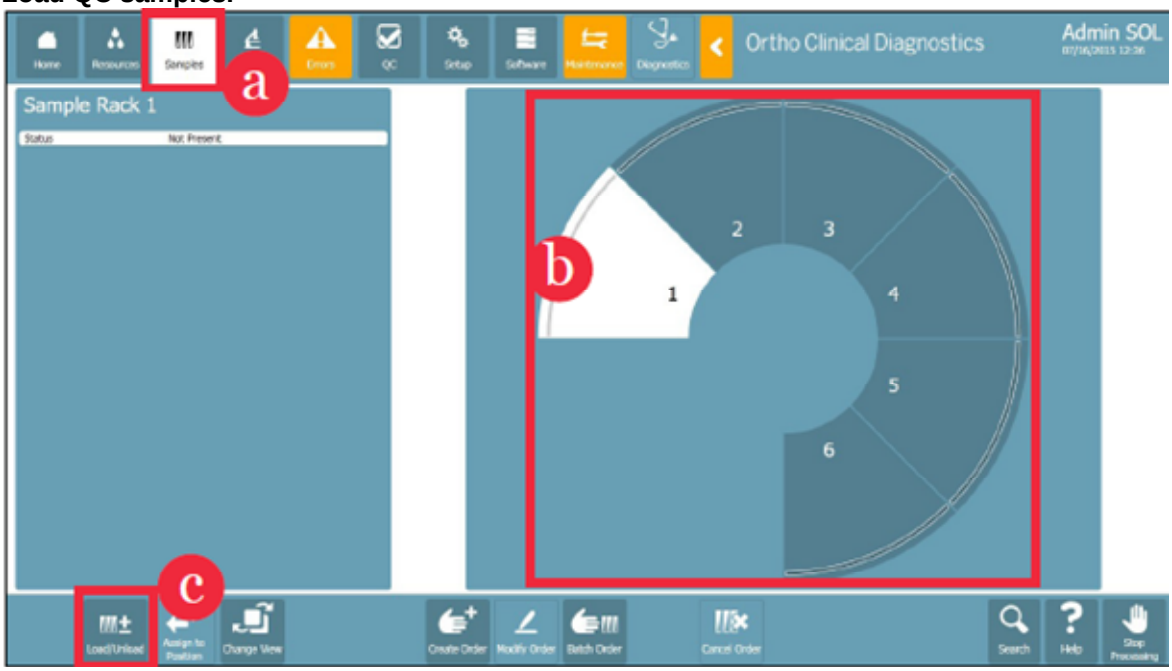
Program QC



Touch Save. NOTE: If need to QC more than one lot of reagent or gel card, touch the 'Reagent Lots' or 'Card Lots' and select one lot# number then Save. Repeat steps to program QC for the remaining lot#.

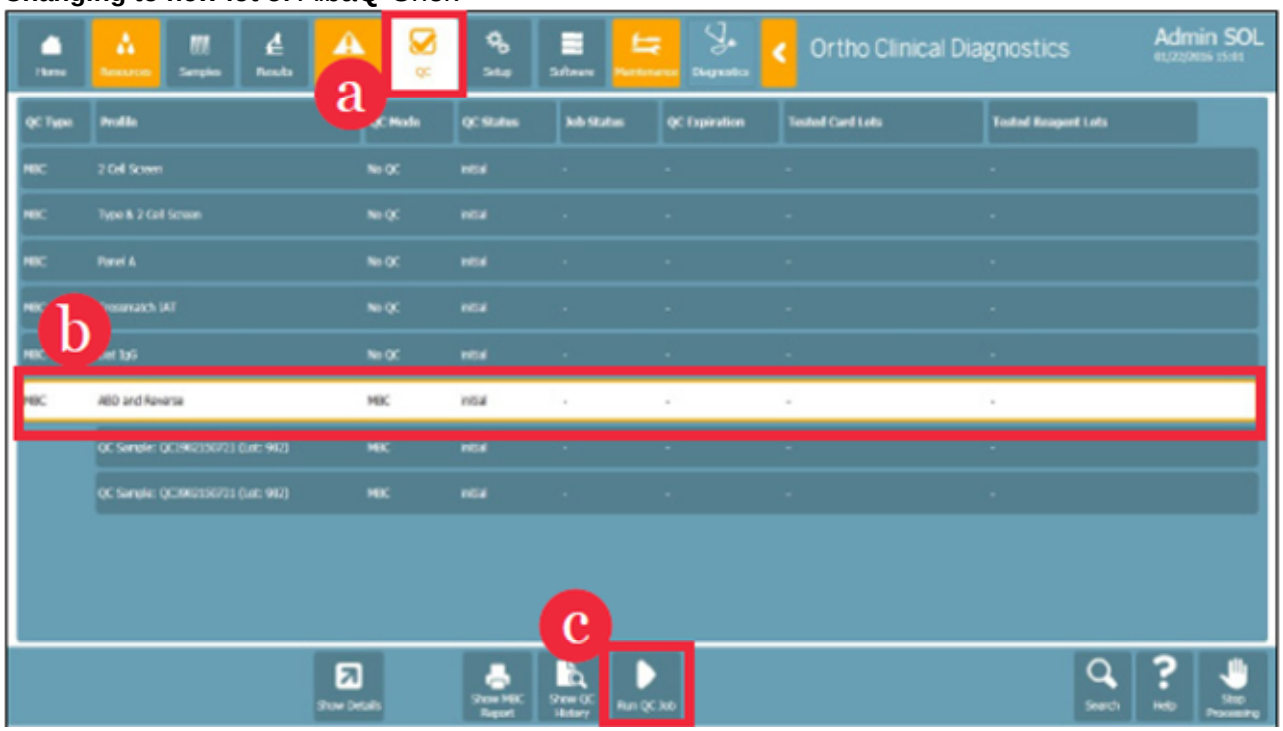


Load QC samples.

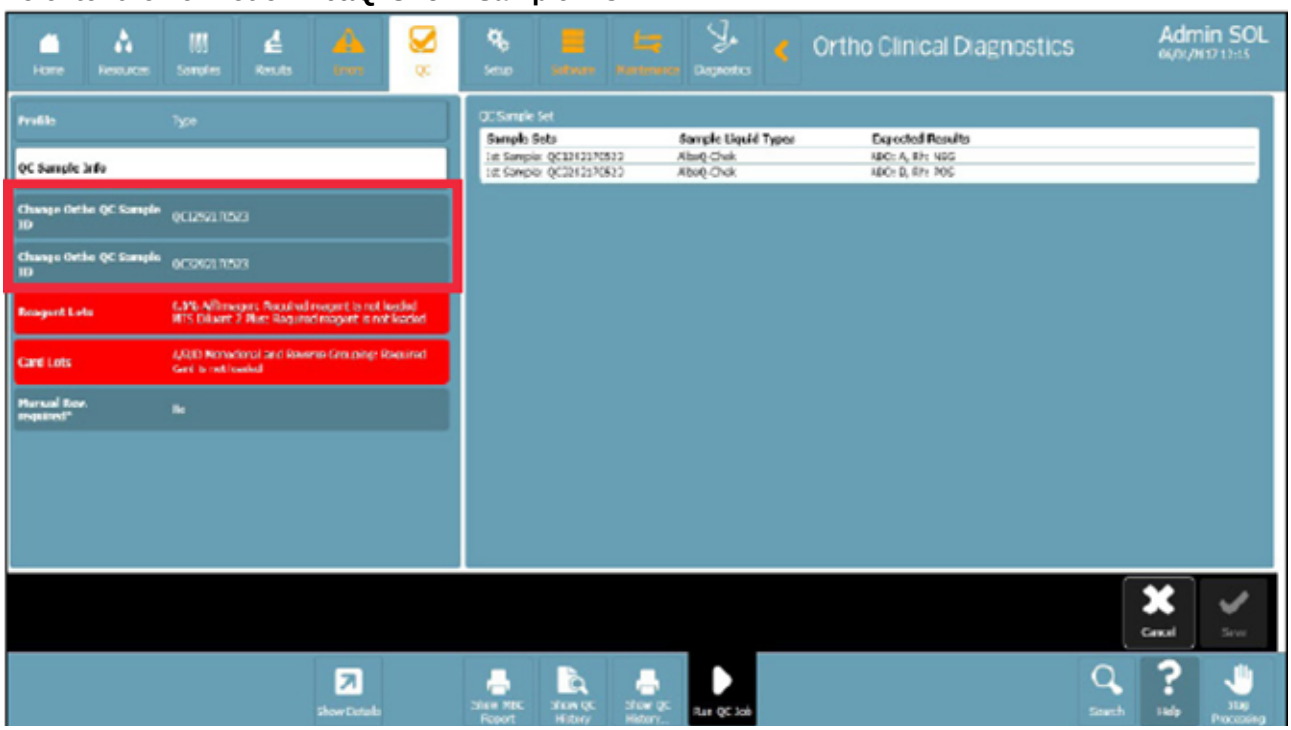


Step	Action
1.	**Changing to new lot of** Alba**Q-C**hek® **(about once a month):** 1. Touch the QC menu button. 2. Select the profile you wish to process and touch the **Run QC Job** action button.
2.	To enter the new lot of Alba**Q-C**hek® samples, touch > **Change AlbaQ QC Sample ID**.
3.	Delete the existing Sample ID and scan the Barcode of the **corresponding Vial#** of the new lot using the Handheld Barcode Scanner. This will enter the QC Lot# twice. If manually typing in the lot number information, type the barcode twice. **Example of Alba Q Check sample name: QC1758YYMMDD.** **1** denotes **Vial #1**. **758** denotes the **last 3 digits of the lot#**. **YYMMDD** is the **expiration date** Alba**Q-C**hek®. .
4.	Repeat steps 1-4 for each MBC Profile (ABORh, ABSC, O Pos Unit Type, Rh Pos Unit Type, and Rh Neg Unit Type, Buffer Card QC).

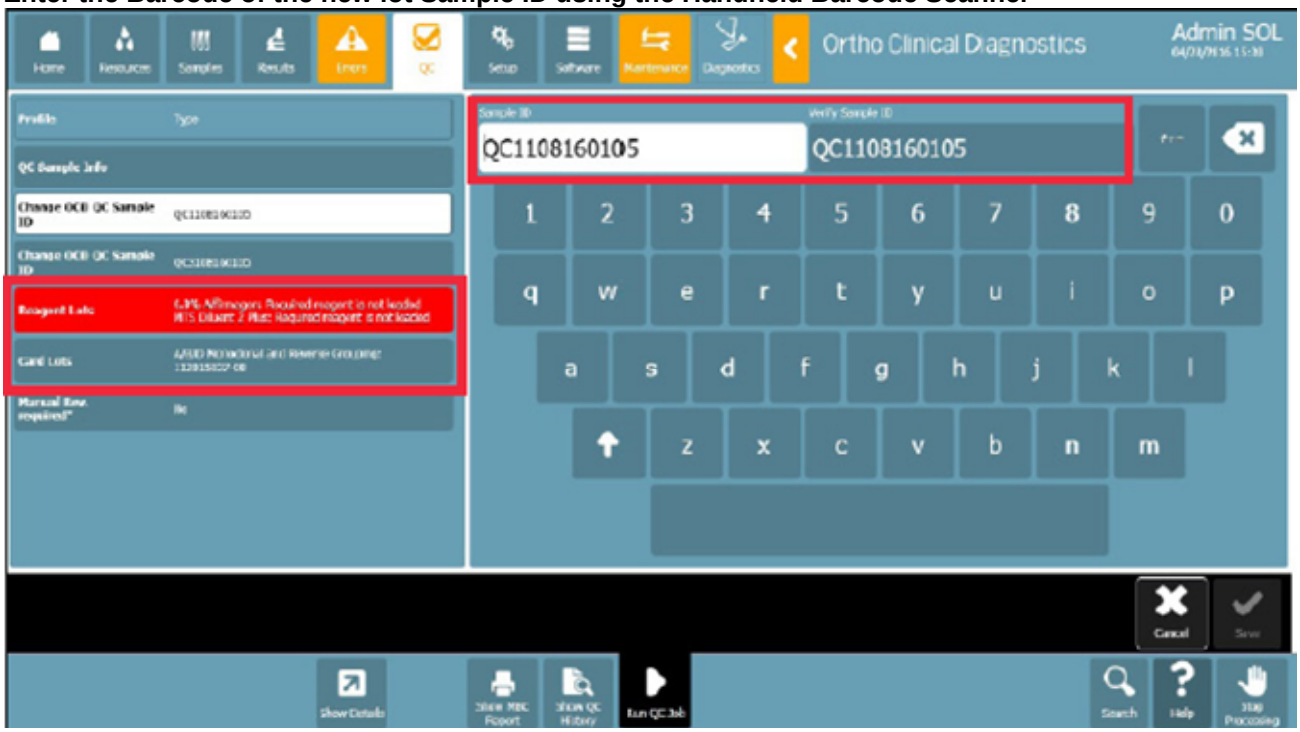
Changing to new lot of Alba**Q-C**hek®



To enter the new lot of Alba**Q-C**hek® **Sample IDs**



Enter the Barcode of the new lot Sample ID using the Handheld Barcode Scanner



9.0 Corrective Action

9.1	**QC Out of Acceptable Range or Failed**
a.	**NOTE: The analyzer will not run patient test for which the QC profile has failed.** Review QC sample preparation, check reagents and gel cards for expiration date and signs of contamination or damage, and verify appropriate barcode labels.
b.	QC that is run with patient testing must be repeated and successful before patient results can be reported.
c.	Depending on the cause of the QC failure, patient impact assessment may need to be performed to decide if previously verified patient tests need to be repeated.

9.2	**Instrument Warning or Error Flag Displayed**
a.	If instrument QC fails or a error is received with a result, you will need to visually review the column reactions in RESULTS to determine the appropriate corrective action steps.
b.	If the error code received is a ? (Indeterminate), review the column reaction by magnifying the view of that column. Determine the cause of the ?. If the ? is caused by dust, fiber, scratch on the card that seen as a BLACK mark in the color picture of the column, it is acceptable to edit the column to the appropriate visually seen reaction. If the ? is on a well that should be Negative and weak reactivity is seen, mix, re-centrifuge the specimen, and repeat the QC for that test.

c.	Error codes that indicate a possible pipetting problem or reagent/sample suspension problem will need to be repeated and should never be corrected to an acceptable/passing result. The following error codes may indicate pipette or reagent/sample suspension issues: **NC** (no cells), **TFC** (Too few cells), **TMC** (Too many cells).
d.	Error codes that indicate possible camera problems will need to be repeated and should never be corrected to an acceptable/passing result. The following error codes may indicate camera problems: **CNF** (Column not found), **LTL** (Light to low), **LTH** (Light too high), **FOC** (Focus error), **PE** (Position error).
e.	Error codes that indicate sample problems or problems with the quality of the gel card should never be corrected to an acceptable/passing result. The following error codes may indicate sample or gel card problems: **WLL** (Wrong liquid level), **CI** (Contrast Interference), **MF** (Mixed Field), **FIB** (Fibrin), **BUB** (Bubble).
f.	If an error code leads to needing to repeat the QC, reject the unacceptable result.
g.	If it is believed that QC specimens have been bacterially contaminated (cloudy) or cross contaminated (caps accidentally switched), open a new QC vial set.

9.3	**Instrument Downtime Action Plan - Alternate Test Method**
	If the Vision is non-operational, the alternate method for Type & Screen is manual tube ABORh and manual Gel ABSC, for Cord DAT IgG is manual tube DAT IgG, for Crossmatch IAT and panel workup is manual Gel, for Unit Confirmation is manual tube.

10.0 Documents and Records

	Vision Maintenance and QC Log initialed by CLS who reviewed that all QC levels were acceptable/PASS.

11.0 Related Documents

11.1	ORTHO Vision® Analyzer ID-MTS® Quick Reference Guide, current revision.
11.2	ORTHO Vision® Analyzer ID-MTS® Gel Cards Reference Guide, current revision.
11.3	ORTHO Vision® Analyzer Procedure, current revision.