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Applicability All Beaumont  
Hospitals

## Routine Testing on the ORTHO VISION Analyzer

Document Type: Policy

### I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide directions for standard testing of patient and donor samples on the ORTHO VISION™ Analyzer.

For information regarding maintenance and quality control (QC) of the ORTHO VISION™, refer to Transfusion Medicine policies, [ORTHO VISION™ Analyzer Maintenance](#) and [ORTHO VISION™ Analyzer QC](#).

### II. POLICY STATEMENT:

The ORTHO VISION™ Analyzer is an instrument designed to automate the testing of blood utilizing ID-MTS™ gel card technology. The ORTHO VISION™ Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. This document provides the technologist with directions on how to prepare and carry out testing of patient and donor samples on the ORTHO VISION™ Analyzer.

### III. DEFINITIONS / ACRONYMS:

- A. **HIS:** Hospital information system.
- B. **LIS:** Laboratory information system.
- C. **BBIS:** Blood Bank Information system
- D. **PSID:** Positive Sample Identification.
- E. **Middleware:** Device that allows two-way communication between the instrument and the BBIS. The instrument can both download orders from the BBIS and upload results to the BBIS.
- F. **Bi-directional Interface:** Device that allow two communication between the BBIS and the LIS where

orders/results are sent between the LIS and the BBIS.

## IV. INSTRUCTIONS RELATING TO SPECIMEN ID NUMBERS / BARCODES:

- A. Specimen ID numbers are used to identify patient samples on the ORTHO VISION™ Analyzer. Barcoded specimen ID numbers are generated from the laboratory information system (LIS) and are routinely used to label the patients' samples. These labels are scanned by the ORTHO VISION™ Analyzer before and during testing.
- B. In the event of a computer downtime (either LIS or HIS) specimens not already labeled with a LIS barcode for testing on the ORTHO VISION™ Analyzer will be labeled with downtime barcode labels.
  - 1. The Blood Bank has pre-generated downtime barcode labels. When indicated, a barcode label will be placed on the sample for **computer downtime** testing purposes, to enable the ORTHO VISION™ to identify samples by scanning barcodes.
  - 2. Do not cover any information from the original sample label when affixing a downtime barcode label to the sample.
  - 3. Band numbers on the original label must be accurate and visible.
- C. **The manual entry of the order numbers for patient samples using the keyboard is not allowed.** The manual entry of order numbers introduces the risk that the wrong results may be generated by the ORTHO VISION™ for the wrong patient.
- D. If the barcode label of a patient sample cannot be scanned automatically by the ORTHO VISION™ or assigned manually to a position by a technologist, the sample must be removed from the ORTHO VISION™ and tested manually.

## V. SPECIMEN COLLECTION AND HANDLING:

- A. The preferred specimen is a properly labeled 6 ml EDTA sample.
- B. EDTA anticoagulated patient samples must be centrifuged.
- C. All cord blood samples for testing must be rimmed out using wooden applicator sticks prior to being centrifuged.
- D. Significantly hemolyzed, lipemic, or icteric samples may interfere with test results and should not be used.
- E. Clot tubes and plasma separator tubes must not be tested on the ORTHO VISION™.
- F. Barcode labels will be placed on sample containers vertically. When placed on the system, the containers will be placed in a vertical orientation with the barcode label faced outward.

## VI. REAGENTS / EQUIPMENT / SUPPLIES:

- 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. MTS Monoclonal Rh Phenotype Cards™
- H. MTS Monoclonal Antigen Typing Cards™ (Individual)
- I. 0.8% AFFIRMAGEN® Reagent Red Blood Cells (reverse typing)
- J. 0.8% SELECTOGEN® Reagent Red Blood Cells (antibody screen)
- K. MTS Diluent 2 PLUS™
- L. MTS Diluent 2™
- M. ORTHO VISION™ Evaporation Caps
- N. ORTHO VISION™ Dilution Trays
- O. Deionized or distilled water
- P. Buffered saline
- Q. Wooden applicator sticks
- R. 10 x 75 mm glass test tubes
- S. 12 x 75 mm glass test tubes
- T. Blood Bank scissors or segment splitter

## VII. QUALITY CONTROL:

- A. The MTS™ Cards are stored in an upright position at 2°C -25°C.
- B. The reagent red blood cells (RBCs) are stored at 2°C - 8°C.
- C. All reagents red blood cells must be fully resuspended prior to being loaded onto the system.
- D. SELECTOGEN® and AFFIRMAGEN® have been validated for 5 days of continuous use on board the analyzer when using the evaporation caps. Reagents shall be initialed and dated when opened and placed on the analyzer.
- E. The MTS Diluent 2 PLUS™ and MTS Diluent 2™ are stored at 2°C - 8°C.
- F. Freshly opened MTS Diluent 2™ and MTS Diluent 2 PLUS™ can be kept on the analyzer up to 24 hours of continuous use.
- G. Each day a technologist shall inspect and replace the on-board MTS Diluent 2™ and Diluent 2 PLUS™.
- H. A visual inspection is performed each day to ensure that the liquid is not discolored, turbid, or shows any signs of contamination. Do not use the diluent if there is any evidence of discoloration, turbidity or other signs of contamination. When a new bottle of diluent is opened, the "open date" and the technologist's initials shall be written on the bottle.
- I. Do not use reagents or gel cards beyond their expiration date.
- J. Reagents and gel cards must be brought to room temperature (18°C -25°C) before use.
- K. 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.

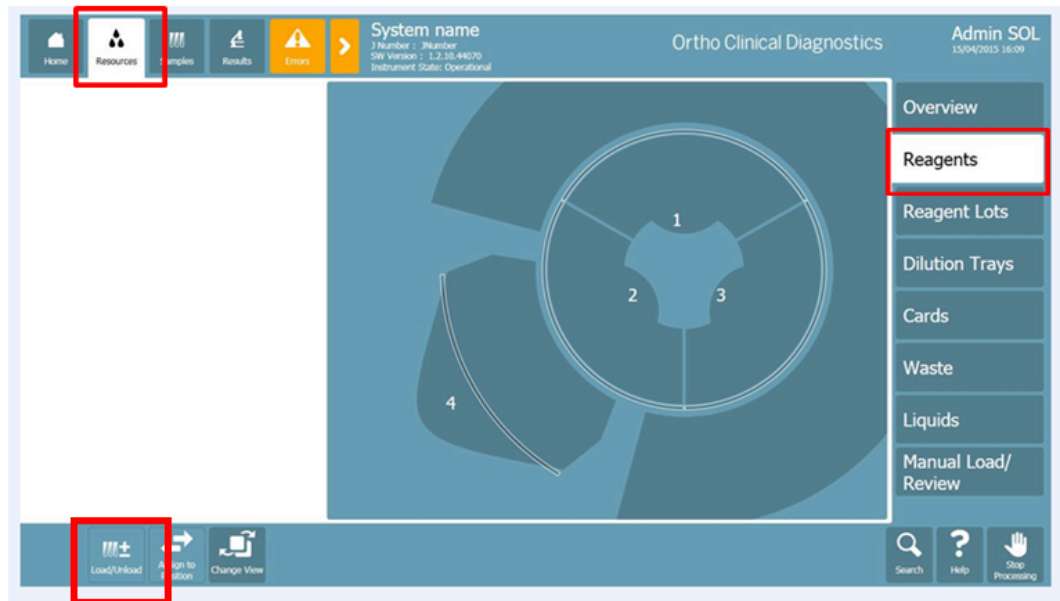
2. The liquid level in the microtube is at or below the top of the gel matrix.
  3. The cards show signs of drying, discoloration, bubbles, crystals, or other artifacts.
  4. Foil seal appear damaged or opened.
- L. Do not store reagent red blood cells that require agitation on-board the system if the system is going to be powered off or in maintenance mode.
- M. Quality control (QC) may NOT be performed in parallel with sample testing, refer to Transfusion Medicine Policy, [ORTHO VISION™ Analyzer QC](#).

## VIII. NOTES:

- A. All testing profiles may not be validated and/or in use at every Corewell location or on every ORTHO VISION analyzer. Only testing that has been validated/implemented and properly quality controlled in each individual Corewell Health Blood Bank and on the respective ORTHO VISION analyzer shall be performed on that instrument.
- B. Verify that daily, weekly, and monthly maintenance have been performed (if indicated), refer to Transfusion Medicine Policy, [ORTHO VISION™ Analyzer Maintenance](#).
- C. Verify that the levels of deionized water, buffered saline and the liquid waste are acceptable.
- D. Allow the MTS™ diluents and reagent test cells to come to room temperature before testing.
- E. Centrifuge patient samples at the centrifuge's calibrated speed (RPM) and time to separate patient plasma and red cells.
- F. Assess all samples and do not use those that are significantly hemolyzed, lipemic, or icteric; this may interfere with test results.

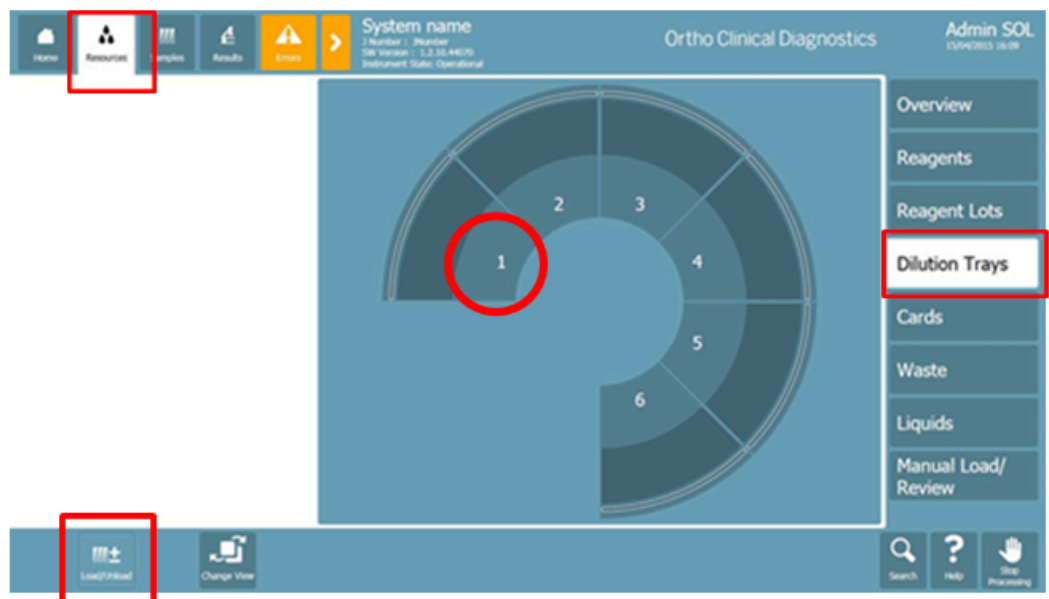
## IX. PROCEDURE:

- A. **Verify appropriate maintenance and QC has been performed.**
- B. **Load Red Cell Reagents and Diluent.** Verify the AFFIRMAGEN® and SELECTOGEN® reagent red blood cells have evaporation caps affixed to them prior to loading. Reagents will be automatically inventoried upon closing of the load station door.
1. Touch RESOURCES.
  2. Touch REAGENTS.
  3. Touch quadrant 1, 2, 3 for reagent red cells.
  4. Touch quadrant 4 for diluents.
  5. Touch LOAD/UNLOAD.
  6. Close the LOAD STATION DOOR.



### C. Load Dilution Trays.

1. Touch RESOURCES.
2. Touch DILUTION TRAYS.
3. Select a quadrant 1-6 and load the dilution tray.
4. Touch LOAD/UNLOAD.
5. Load the dilution trays. Additional dilution trays can be added by touching additional quadrants.
6. Close the LOAD STATION DOOR.



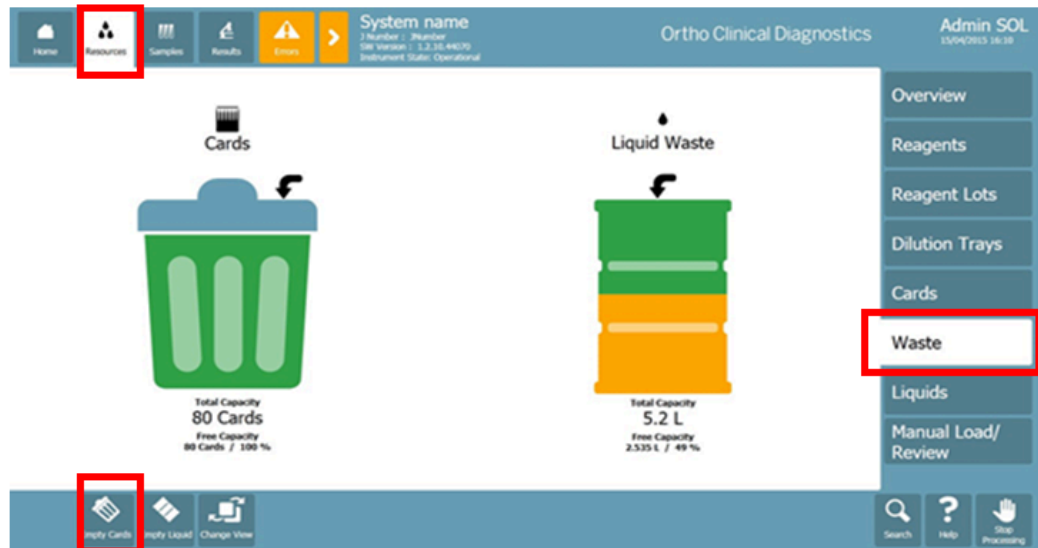
### D. Load Cards.

1. Touch RESOURCES.
2. Touch CARDS.
3. Touch LOAD/UNLOAD.
4. Open the SUPPLY DRAWER and load sleeves of cards.
5. Close the SUPPLY DRAWER.



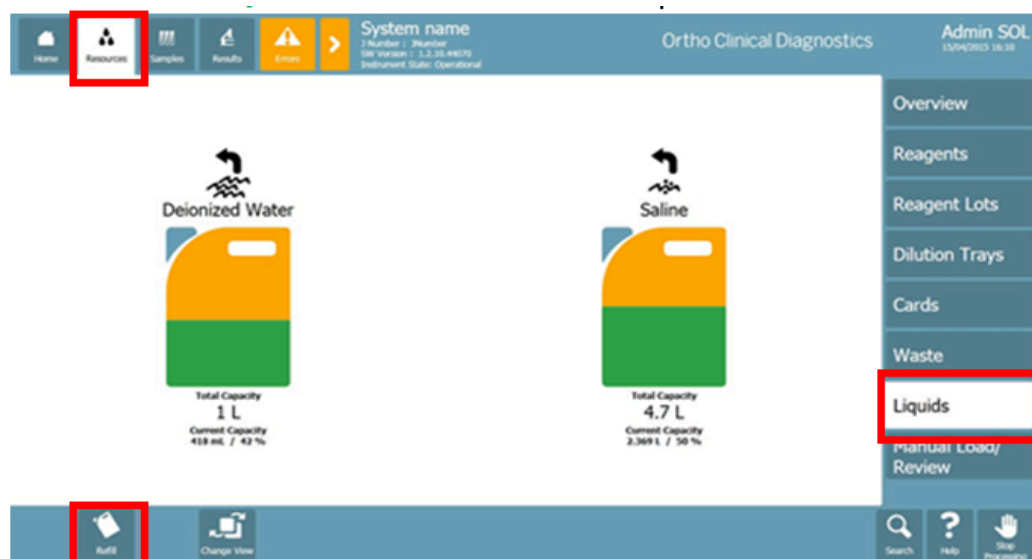
#### E. Empty Card Waste.

1. Touch RESOURCES.
2. Touch WASTE.
3. Touch EMPTY CARDS.
4. Open the CARD WASTE DRAWER, remove the white container and dispose of the contents.
5. Replace the white container on the analyzer and close the drawer.
6. Answer YES to the question, "Cards were emptied?"



#### F. Replace Liquids.

1. Touch RESOURCES.
2. Touch LIQUIDS.
3. Touch REFILL.
4. Remove the liquid container. Refill the buffered saline (in the clear container) and DI H<sub>2</sub>O (in the blue container) to the top and replace the container on the analyzer. This must be done every time the liquid waste is emptied.
5. Empty the liquid waste container. Put on the dry cap.
6. Close the liquid system door.
7. The confirmation dialogue asks for a confirmation that both the buffered saline and deionized water containers have been completely filled and the LIQUID WASTE BOTTLE has been emptied. Select YES to confirm. If you select NO, the refill levels will not reset.
8. Wait while the system executes a flush.



G. **Load Samples.** Samples can remain on-board the system for up to 4 hours. If a sample is detected on-board the system at start up, the sample is marked as unusable. The analyzer will inventory the samples just placed on-board.

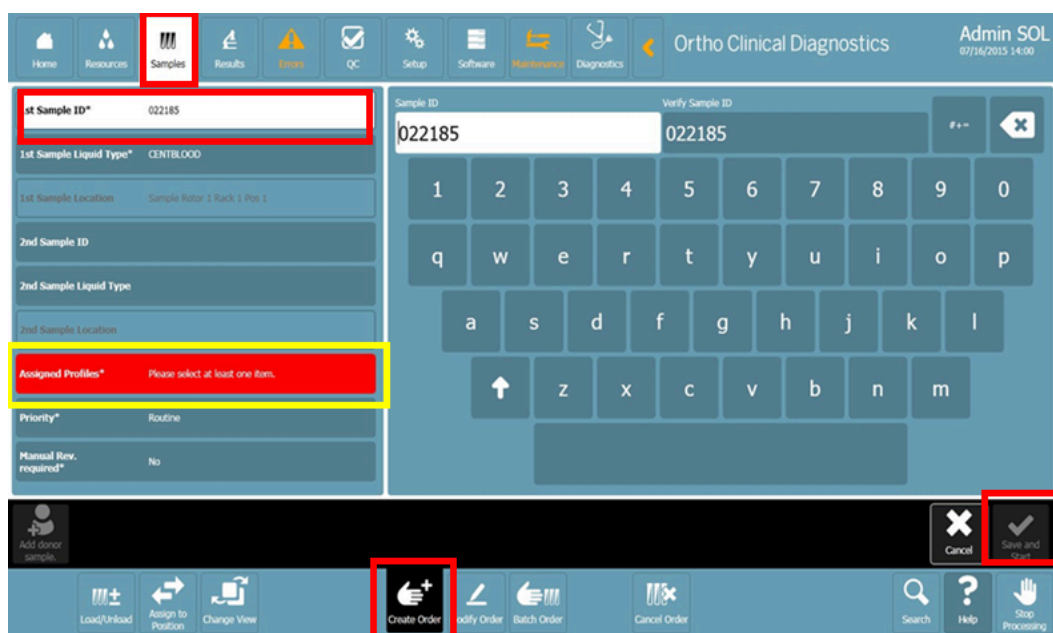
1. Before the samples are loaded, ensure that:
  - a. Tubes are free of bubbles and foam.
  - b. Barcode labels are properly affixed to sample tubes.
  - c. Samples have been centrifuged.
  - d. Cord blood samples were rimmed out using wooden applicator sticks prior to being centrifuged.
  - e. Caps/stoppers are removed from samples, reagents and diluents.
2. Load the samples.
  - a. Touch the SAMPLES MENU.
  - b. Select the quadrant you wish to load.
  - c. Touch LOAD / UNLOAD.
  - d. Place the samples onto the load station, using the provided handles on the rack.
  - e. If you have more than one rack to load touch the other quadrants and load your racks.
  - f. Close the LOAD STATION DOOR when you are done.





H. **Create an Order.** This method of manual test ordering is required when the bi-directional interface is not available, or the system is not connected to a LIS.

1. After the samples that require manual ordering are loaded, they will turn orange because there is no order assigned to the sample yet.
2. Click the orange sample (not the sample rack “wedge”).
3. Touch CREATE ORDER.
4. Verify the correct sample barcode is in the field 1st Sample ID.
5. Verify the field 1st Sample liquid type field says CENTRBLOOD.
6. Touch ASSIGNED PROFILES (will be highlighted in red) and select the profile.
7. Touch SAVE and START.



I. **Create a Crossmatch Order.** This method of manual crossmatch ordering is required when the bi-

directional interface is not available, or the system is not connected to a LIS. Up to 20 donors can be assigned to each crossmatch sample.

1. Ensure the donor sample is prepared for crossmatch.
  - a. Obtain a segment from the donor unit to be crossmatched.
  - b. Label a glass tube with a large barcode label from the donor unit.
  - c. Using Blood Bank scissors or a segment splitter, cut the top and the bottom off the segment and fully empty the segment into the tube.
  - d. The ORTHO VISION™ requires 7mm of donor sample in the test tube for processing. If one segment does not give enough sample for 7 mm, add additional segments until the 7 mm is reached.
2. Create the crossmatch order.
  - a. Load the patient and donor samples like you would normally (see below in this same step on how to prepare donor samples for crossmatches).
  - b. Click the patient sample you wish to assign crossmatches to.
  - c. Touch CREATE ORDER.
  - d. Touch ASSIGNED PROFILES and select Crossmatch (XMG).
  - e. Touch ADD DONOR SAMPLE in the bottom left of the screen.
  - f. Touch Sample ID Donor 1 and hit "List" in the lower left area of the keyboard screen. This pulls up all scanned patient and donor samples on the ORTHO VISION™.
  - g. Select the donor sample you wish to crossmatch.
  - h. Touch Sample Type Donor 1 and select CENTRBLOOD.
  - i. Repeat the same steps for Donor 2 through Donor 20 (if needed).
  - j. Touch SAVE AND START.

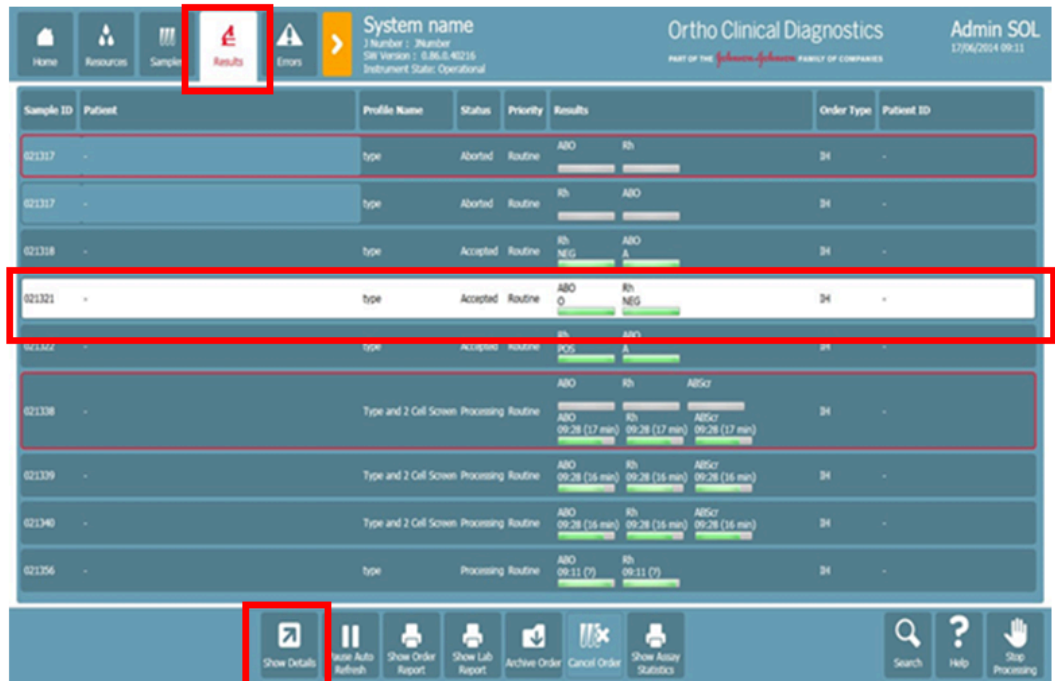
#### J. Review Results.

All sample results are reviewed by the instrument software based on user defined criteria set for each test profile.

Result that meet that criteria are set to Auto accept and are sent to the BBIS. Any results that fail the criteria or have any questionable or discrepant results must be reviewed and solved before reporting.

The results screen allows you to view current active orders on the system. You can also print reports, view details, and cancel orders using the buttons located along the bottom of the screen. When the results view is opened from the results list, the card images are displayed from the front side.

1. Touch RESULTS to access this screen.
2. Select the sample ID.
3. Touch SHOW DETAILS.
4. If a column grade is above the defined threshold, the result is automatically sent.
5. If a column grade result is equal to or below the defined threshold or the card has an error, the affected card is placed in the MANUAL REVIEW RACK.



#### K. Modify and Accept Results.

1. Use the manual review option to resolve indeterminate results when a test has been flagged.
2. Retrieve the card that has the error or indeterminate result by going to RESOURCES > MANUAL LOAD REVIEW > LOAD/ UNLOAD.
3. Touch RESULTS.
4. Select the Sample to be edited.
5. Touch SHOW DETAILS.
  - a. The column image has a border with a warning color to indicate that manual review is required.
6. Touch EDIT GRADES.
7. Scan the barcode of the card with the results to be edited.
8. Touch the result that needs to be manually reviewed.
9. Enter the new, manually reviewed result.
  - a. All results MUST be interpreted from the card, NOT from the result screen on the ORTHO VISION™.
  - b. After every edited grade, the test analysis results are recalculated automatically. Column grades that have been edited are indicated with an asterisk \* on the results screen and the Order Report.
10. Touch NEXT.
11. Touch NEXT (if necessary, a comment can be added when modifying a result).
12. Enter user PASSWORD.

13. Touch CONFIRM PASSWORD.
14. Touch ACCEPT RESULTS.

Ortho Clinical Diagnostics Admin SOL 17/04/2015 16:41

Sample ID: QC1579130331 Profile Name: anura type Status: Review required (Completed) Priority: STAT Results: ABO: A\* Rh: NEG\* Order Type: QC

Tests: A/B/D and Reverse Group

ABO Rh  
A\* NEG\*

QC Status: failed  
Expected Results:  
ABO Rh  
A NEG

Card: 837 (A/B/D Monoclonal and Reverse Grouping)  
ID: 46919 | Lot: 052014037.65 | Expiration: 30/03/2015

Previous Next

Anti-A	Anti-B	Anti-D	Ctrl	A1-Cells	B-Cells
4+	0	0	?	0	3+

Original Grade  
Threshold +

Results: ABO Original ABO Edit Rh Original Rh Edit  
? A\* ? NEG\*

Flags: assay reading errors, indeterminate result, result expired, maintenance required

Change to Color Change to Back

Back Show Details Show Intelligence Report Send To LIS Edit Grades Edit Results Reject Result Accept Result Search Help Resume Processing

**L. Send Results to LIS.** Manually accepted results must be sent to the LIS.

1. In the RESULTS SCREEN touch SEND TO LIS.

Ortho Clinical Diagnostics Admin SOL 17/04/2015 16:41

Sample ID: QC1579130331 Profile Name: anura type Status: Review required (Completed) Priority: STAT Results: ABO: A\* Rh: NEG\* Order Type: QC

Tests: A/B/D and Reverse Group

ABO Rh  
A\* NEG\*

QC Status: failed  
Expected Results:  
ABO Rh  
A NEG

Card: 837 (A/B/D Monoclonal and Reverse Grouping)  
ID: 46919 | Lot: 052014037.65 | Expiration: 30/03/2015

Previous Next

Anti-A	Anti-B	Anti-D	Ctrl	A1-Cells	B-Cells
4+	0	0	?	0	3+

Original Grade  
Threshold +

Results: ABO Original ABO Edit Rh Original Rh Edit  
? A\* ? NEG\*

Flags: assay reading errors, indeterminate result, result expired, maintenance required

Change to Color Change to Back

Back Show Details Show Intelligence Report Send To LIS Edit Grades Edit Results Reject Result Accept Result Search Help Resume Processing

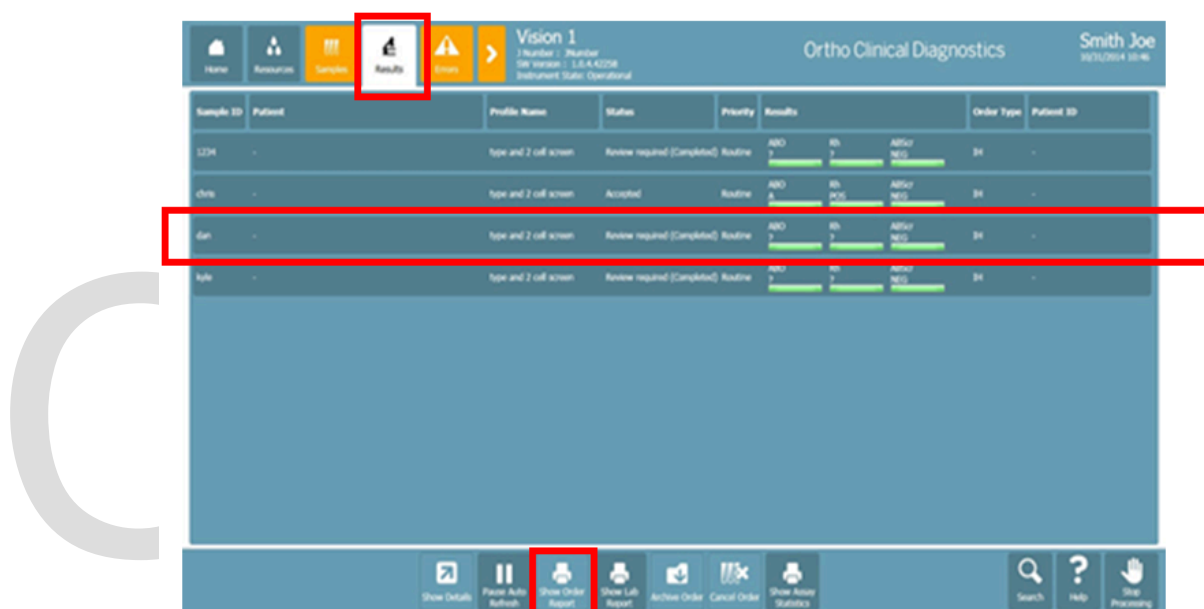
**M. Reject Results.** Rejected results can still be edited or accepted.

1. Touch the RESULTS menu button.

2. Touch a row to select a test.
3. Touch the SHOW DETAILS action button.
4. Review the results before rejecting the result.
5. Touch the REJECT RESULT action button.
6. The “Rejected Result” icon appears next to this result on the Details screen.

#### N. Printing Reports.

1. Touch RESULTS.
2. Touch the SAMPLE ID.
3. Touch SHOW ORDER REPORT.



## X. SYSTEM CODES AND FLAGS:

1. Codes generated by the analyzer indicate conditions that require operator attention. For example, if a bubble is detected in a column during the post processing check, the result is not reported and the system assigns the code 'BUB' to the result to call attention to the bubble that was detected.
2. See attachment *ORTHO VISION™ Analyzer System Flags and Codes* for a detailed list of results flags and codes.

## XI. RESULTS AND INTERPRETATION:

### A. Autoverification of Results

1. All sample results are reviewed by the instrument software based on user defined criteria set for each test profile.
  - a. Graded reactions must be of specific strengths to be considered valid.
  - b. Results that meet that criteria are set to Auto accept and are sent to the BBIS.

- c. Any results that fail the criteria will be held by instrument for manual review of the results and confirmation of interpretation before sending result to the BBIS.
  - d. Any sample with instrument flags will stop autoverification so that the tech can review the instrument results and sample to properly identify the best course of action for resulting the patient.
  - e. Any results that fail the criteria or have any questionable or discrepant results must be reviewed and solved before reporting.
  - f. All tests must be interpreted based on the Blood Bank procedures, not necessarily how the ORTHO VISION™ interprets them.
2. All normal results from the analyzers with valid grading and no evidence of discrepancy with historical data in the BBIS will be auto-verified in the BBIS and automatically interfaced to the laboratory's LIS for reporting in the patient chart.
  3. All results that fail the autoverification criteria defined in the Transfusion Medicine policy, Blood Bank Autoverification Policy will be sent to the Interface Manager in the BBIS for manual resulting/ interpretation in accordance with steps outlined in the SafetraceTx (Blood Bank) Application procedure.

## B. Valid Graded ABO and Rh Reactions in Gel Testing

Valid graded ABO and Rh reactions in gel testing are defined in the following table:

If the test is:	Then the graded result must be:
Forward ABO grouping	0 or 3 - 4+
Rh typing	0 or 4+
Control	Negative
Reverse Typing	0 or 1 - 4+

- A. Negative Result – No agglutination and no hemolysis of the red blood cells is a negative test result.
- B. Positive Result – Agglutination and/or hemolysis of the red blood cells is a positive test result. Agglutination must be of the strength listed in the table above to be considered a valid graded reaction. Refer to Invalid Graded Reactions, below, if applicable. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few red blood cells may form a button in the bottom of the microtube in some positive reactions. The test cannot be interpreted if agglutination occurs in the control well.
- C. Rh Typing positive results <4+ are considered positive for Weak D and potential for D Variant. These patients should be interpreted in accordance with *Rh Typing Interpretation (for Weak Rh reactions)* Table below.
  1. D Variant Analysis will be performed on all pregnant females that are determined to be possible D variants. Refer to D Variant Testing for Pregnant Females in the Transfusion Medicine procedure, Weak D Testing.
  2. Once a patient has been determined to be a possible D variant, they must be treated as such until either molecular testing has been performed, the patient is over 50 for females or 15 for males unless otherwise determined by the Transfusion Service Medical Director or designee. If no D variant testing has been performed, once males are over 15 or females are over 50, they can be changed to D positive on subsequent type testing

performed.

- D. Mixed Field reactions are considered an invalid graded reaction and must be investigated. Refer to *Invalid Graded Reactions*, below.

ABO and Rh Interpretation by Gel Method						
Red Blood Cell Typings				Reverse Grouping		Interpretation
Anti-A Microtube	Anti-B Microtube	Anti-D Microtube	Control Microtube	Buffered Gel A <sub>1</sub> Cell Microtube	Buffered Gel B Cell Microtube	
0	0	4+	0	1 - 4+	1 - 4+	O Positive
0	0	0	0	1 - 4+	1 - 4+	O Negative
3 - 4+	0	4+	0	0	1 - 4+	A Positive
3 - 4+	0	0	0	0	1 - 4+	A Negative
0	3 - 4+	4+	0	1 - 4+	0	B Positive
0	3 - 4+	0	0	1 - 4+	0	B Negative
3 - 4+	3 - 4+	4+	0	0	0	AB Positive
3 - 4+	3 - 4+	0	0	0	0	AB Negative
		1 - 3+	0			Possible Weak D; refer to the Weak Rh Typing Interpretation table below
+ or 0	+ or 0	+ or 0	+	+ or 0	+ or 0	Cannot interpret; refer to the invalid graded reactions section below.

+ = Presence of agglutination      0 = Absence of agglutination

Rh Typing Interpretation (for Weak Rh Reactions)					
Patient Age/ Sex/ Description	Anti-D Graded Reactions by Gel Method	Control	Rh Interpretation	Result Comment Code	Message Description
Neonates (performed for RhIG purposes)	1 - 3+	0	Rh Negative	WKDPOS	Weak D result is positive. Infant's mother should receive a post-partum dose of RhIG
Females ≤ 50 years old	1 - 3+	0	Rh Negative	DVAR	The Rh results suggest a possible D variant. Without genotyping of the RHD gene for additional information, for purposes of transfusion, the patient will be treated as Rh negative. For pregnancy, consider managing the patient as Rh negative.



Males $\leq 15$ years old	1 - 3+	0	Rh Negative	CDDVAR	The Rh results suggest a possible D variant. Without genotyping of the RHD gene for additional information, for purposes of transfusion, the patient will be treated as Rh negative.
Females >50 or Males >15 years old	1 - 3+	0	Rh Positive	DVARP	The Rh results suggest a possible D Variant, the patient will be treated as <b>Rh positive</b> .

## C. Invalid ABO and Rh Graded Reactions

### A. Reactive Monoclonal Control.

1. The control must be non-reactive to interpret the ABO/Rh. If false positive reactions (e.g. Rouleaux, red blood cells coated with immunoglobulins, etc.) occur in the control well, the ABO and Rh type cannot be determined. Additional testing will be necessary to resolve this false positive reaction; refer to Transfusion Medicine policy, [Resolution of ABO and Rh Discrepancies](#). If the technologist is able to resolve the ABO or Rh discrepancy based on this policy in the Blood Bank computer system, then the valid interpretation will be entered into the Blood Bank computer system.

## D. ABO and Rh Discrepancies

### A. An ABO or Rh discrepancy may occur if:

1. The ABO or Rh graded reactions are not valid.
2. The graded reactions do not yield a valid interpretation.
3. The control is reactive.
4. The current type does not match the historical type in the Blood Bank computer system.

### B. If an ABO discrepancy remains unresolved, the technologist will:

1. Proceed as described in Transfusion Medicine policy, [Resolution of ABO and Rh Discrepancies](#).
2. Use group O, immediate-spin crossmatch compatible RBCs if transfusion is necessary. Note that immediate-spin crossmatches may not be required for neonates under four months old as indicated in *Newborn Compatibility Testing Guidelines*.

### C. If a Rh discrepancy remains unresolved, the technologist will:

1. Proceed as described in Transfusion Medicine policy, [Resolution of Rh Discrepancies](#).
2. Use Rh negative, immediate-spin crossmatch compatible RBCs if transfusion is necessary. If Rh negative supply is depleted it may become necessary to transfuse Rh positive RBCs. Note that immediate-spin crossmatches may not be required for neonates under four months old as indicated in *Newborn Compatibility Testing Guidelines*.



## E. RELEASE OF RESULTS FOR BBIS INTERFACE MANAGER

- A. Codes indicate conditions that require operator attention. For example, if a bubble is detected in a column during the post processing check, the result is not reported and the system assigns the code 'BUB' to the result to call attention to the bubble that was detected.
- B. All sample results are reviewed by the instrument software. It is set up for Auto Accept. Any questionable or discrepant results must be resolved before reporting.
- C. See attachment *ORTHO VISION™ Analyzer System Flags and Codes* for a detailed list of results flags and codes.

## XII. SPECIAL SAFETY PRECAUTIONS

- A. Universal precautions are indicated when handling patient specimens, reagents and quality control materials. Spills and accidents should be addressed immediately. Refer to the appropriate safety data sheet (SDS) for specific reagent information.
- B. **Emergency Shutdown**
  - 1. To perform an emergency shutdown, touch the *Stop Processing* button from any screen and choose the *Perform Urgent Stop* option. The system will immediately power down and all doors will automatically unlock to allow for specimen and reagent removal. Note: If screen is frozen and *Stop Processing* button is unavailable it may be necessary to physically power off instrument at the switch.
  - 2. An emergency shutdown should only be performed if truly an emergency and normal shutdown procedures are not available.
  - 3. All test processes are stopped immediately once an urgent stop is requested. These tests will be failed and any results are lost. Pending tests will not begin.

## XIII. SPECIAL HANDLING:

- A. **Handling of Specimens During Instrument Downtime**
  - 1. When analyzer is unavailable during maintenance or unexpected downtime, patient testing must be performed using manual tube or gel methods if another Vision Analyzer is unavailable.
- B. **Pipette Carry Over**
  - 1. The analyzer performs probe wash after each sample to prevent carry over. Additionally the daily probe decontamination performed as part of daily maintenance also prevent carry over.
  - 2. A sample with a very high-titered antibody (>1:1024) when tested for antibody screening or panel identification may intermittently cause carry-over in the next pipetted sample.
    - a. all positive screen results are reviewed and/or investigated. If carry-over is suspected daily maintenance and quality control must be performed.

## XIV. REFERENCES:

- A. AABB *Standards for Blood Banks and Transfusion Services*, current edition.
- B. AABB *Technical Manual*, current edition.
- C. College of American Pathologists, Transfusion Medicine Checklist, current edition.
- D. Ortho Clinical Diagnostics, Rochester, NY, Ortho Vision General Operator Training Manual, Publication J56102.
- E. ORTHO VISION® Analyzer ID-MTS Gel Cards Reference Guide J40050.
- F. ORTHO VISION® Analyzer ID-MTS Gel Cards Self-Service Customer Procedures Guide J40055ENNA.
- G. ORTHO VISION® Analyzer Electronic Library, Software version 5.3.0.0.
- H. Ortho Clinical Diagnostics, Rochester, NY, Electronic Publication number J56102.
- I. ID-Micro Typing System® Implementation Guide 6902200.

### Attachments

[ORTHO VISION Analyzer System Flags and Codes \(03/21/2024\)](#)

[ORTHO VISION Analyzer System Overview \(03/21/2024\)](#)

[ORTHO VISION Error Handling \(03/20/2024\)](#)

### Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	Pending
	Muhammad Arshad: Chief, Pathology	Pending
	Kristina Davis: Staff Physician	7/12/2024
	Karrie Torgerson: Medical Technologist Lead	7/5/2024
	Hassan Kanaan: OUWB Clinical Faculty	7/2/2024
	Jeremy Powers: Chief, Pathology	7/1/2024

Policy and Forms Steering Committee (if needed)	Masood Siddiqui: Staff Pathologist	6/26/2024
	Ryan Johnson: OUWB Clinical Faculty	6/25/2024
	John Pui: Chief, Pathology	6/25/2024
	Kelly Sartor: Mgr, Division Laboratory	6/25/2024
	Kristen DiCicco: Mgr, Laboratory	6/25/2024
	Fatima Bazzi: Medical Technologist Lead	6/25/2024
	Ashley Beesley: Mgr, Laboratory	6/18/2024
	Katherine Persinger: Mgr, Laboratory	6/18/2024
	Teresa Lovins: Supv, Laboratory	6/18/2024
	Suzanne Chahine: Medical Technologist Lead	6/18/2024
	Hilary Morey: Medical Technologist Lead	6/18/2024
	Kelly Sartor: Mgr, Division Laboratory	6/17/2024
	Kelly Sartor: Mgr, Division Laboratory	6/17/2024

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## Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne