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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:

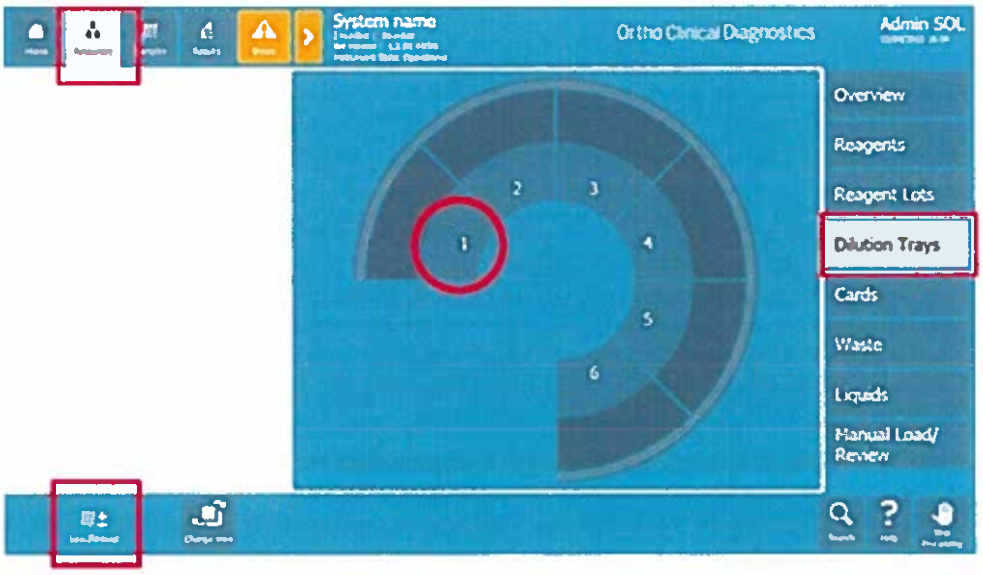
A. **Verify appropriate maintenance and QC has been performed.**

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.

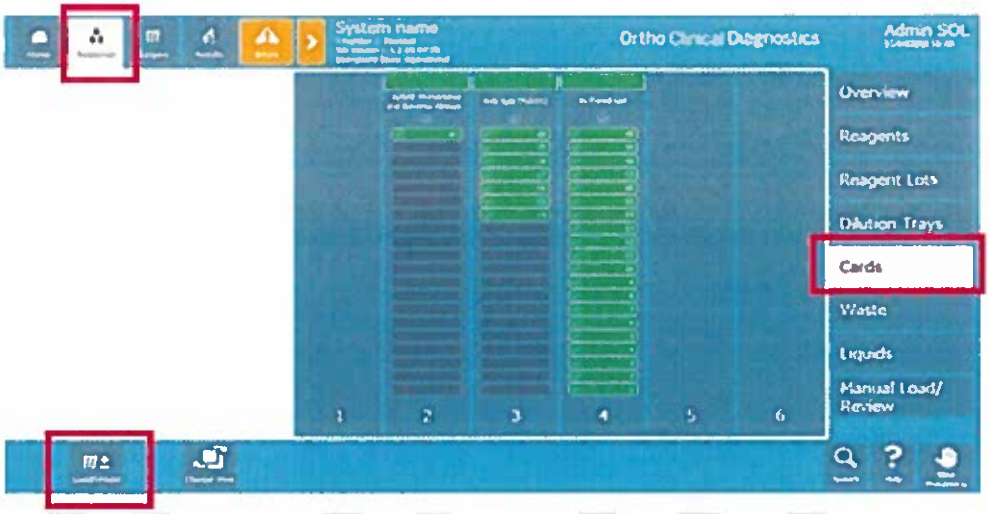
C. **Load Dilution Trays.**

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.



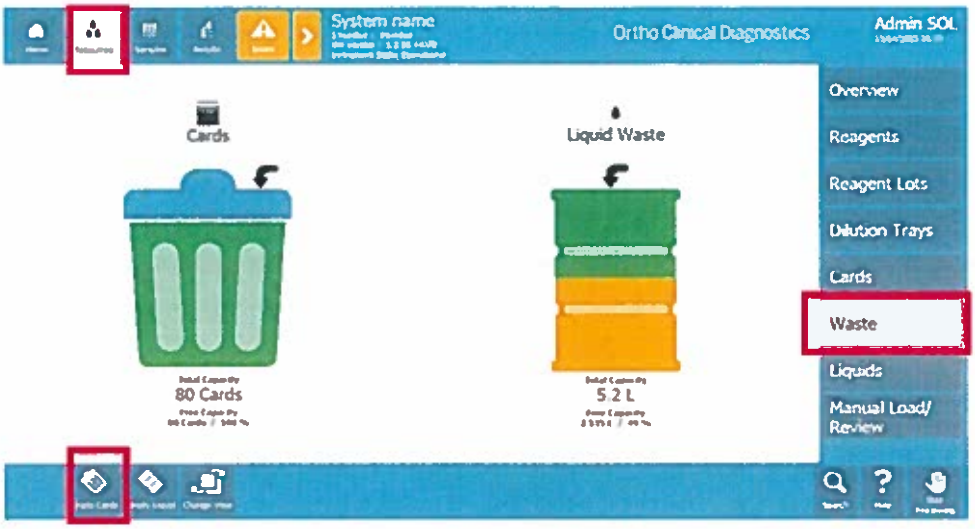
D. **Load Cards.**

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.



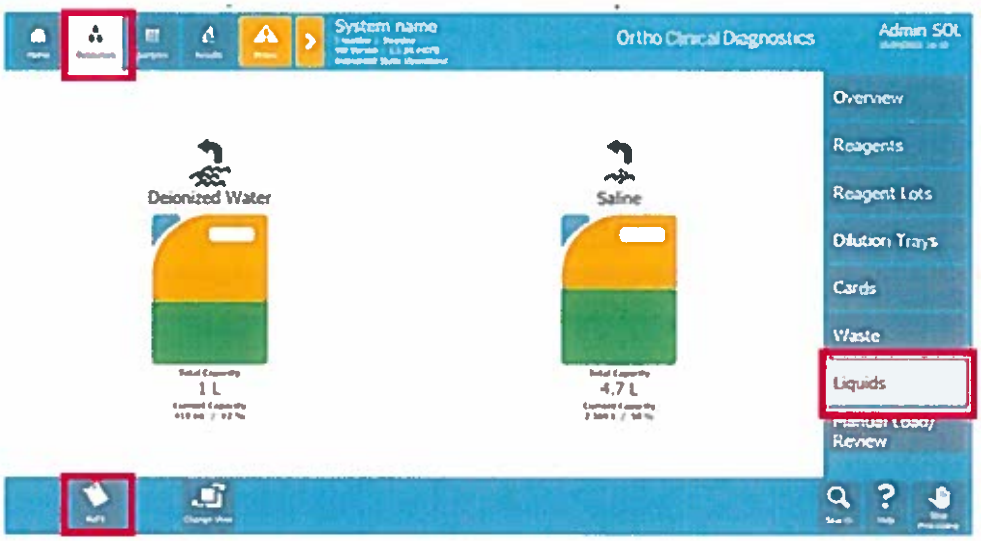
E. **Empty Card Waste.**

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?"



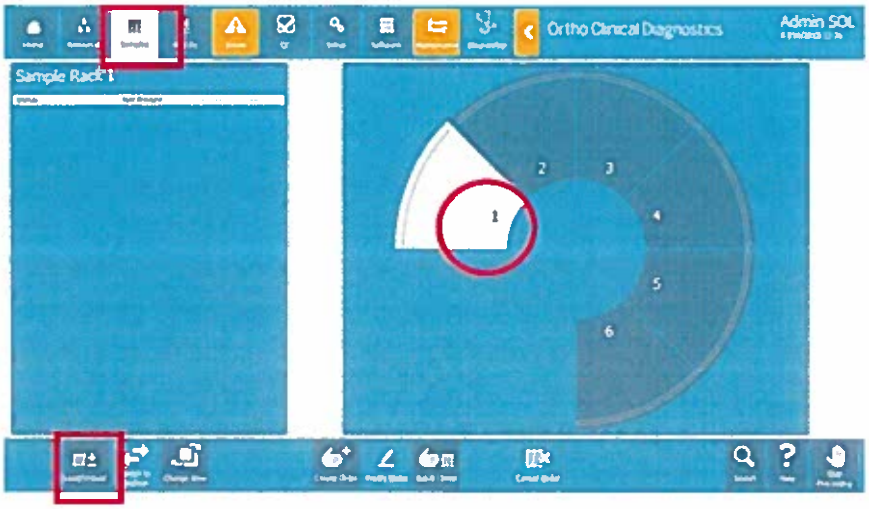
F. **Replace Liquids.**

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_2O (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.



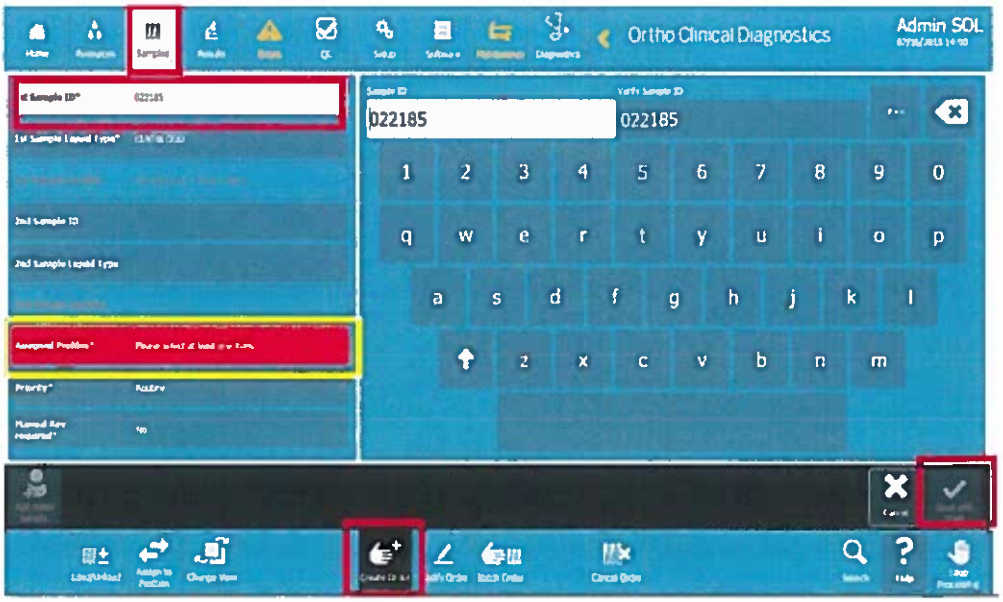
G. **Load Samples.** Samples can remain on-board the system for up to 4 hours. If a sample is detected on-board the system at start up, the sample is marked as unusable. The analyzer will inventory the samples just placed on-board.

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.

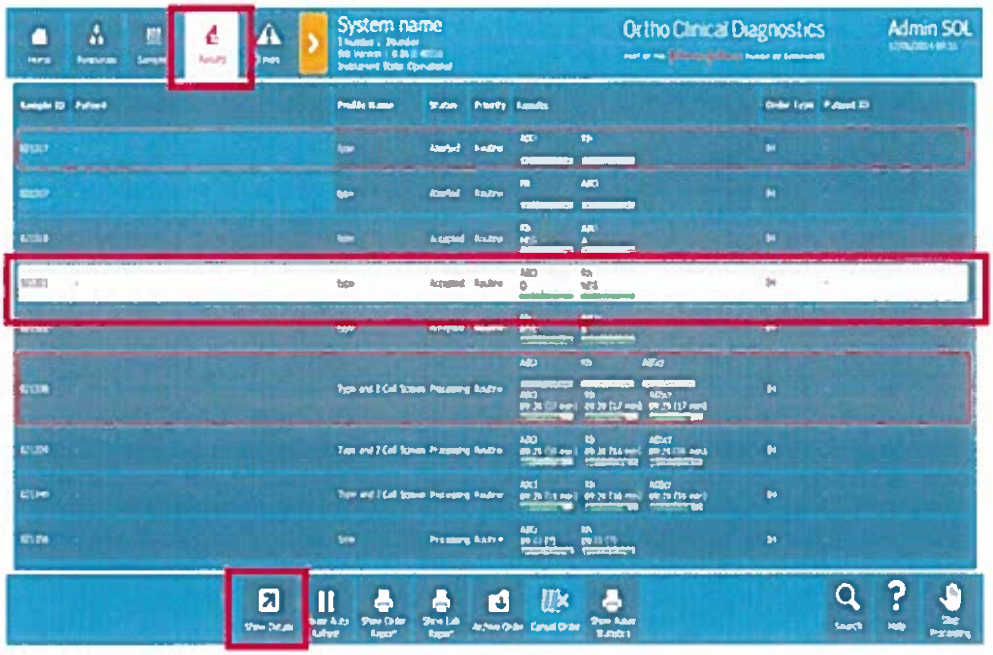
1. Ensure the donor sample is prepared for crossmatch.
    a. Obtain a segment from the donor unit to be crossmatched.
    b. Label a glass tube with a large barcode label from the donor unit.
    c. Using Blood Bank scissors or a segment splitter, cut the top and the bottom off the segment and fully 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.

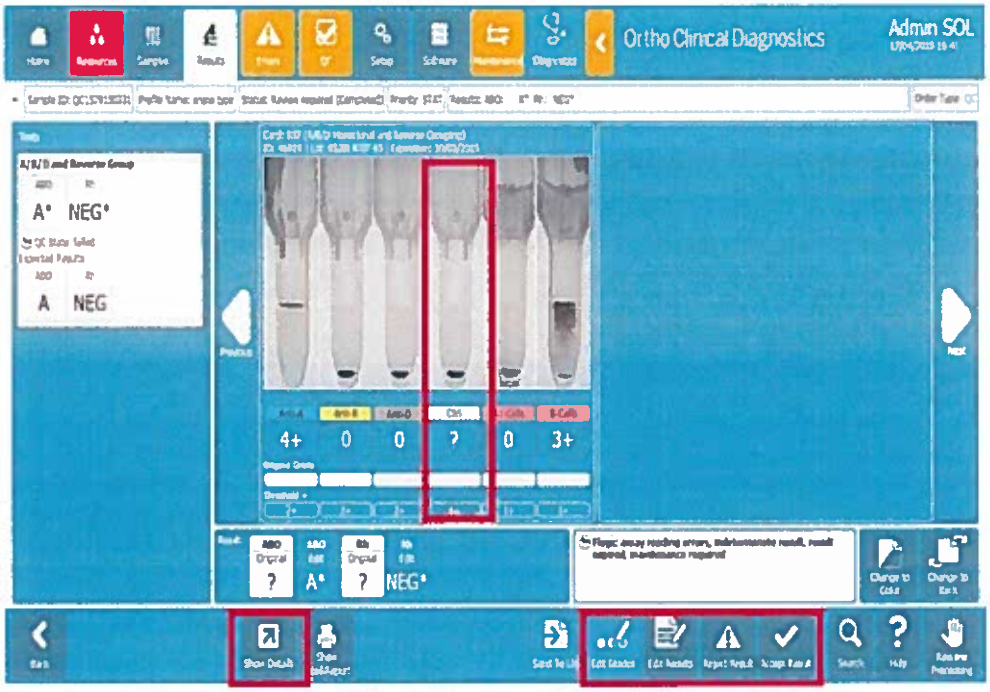
1. Touch RESULTS to access this screen.
2. Select the sample ID.
3. Touch SHOW DETAILS.
4. If a column grade is above the defined threshold, the result is automatically sent.
5. If a column grade result is equal to or below the defined threshold or the card has an error, the affected card is placed in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



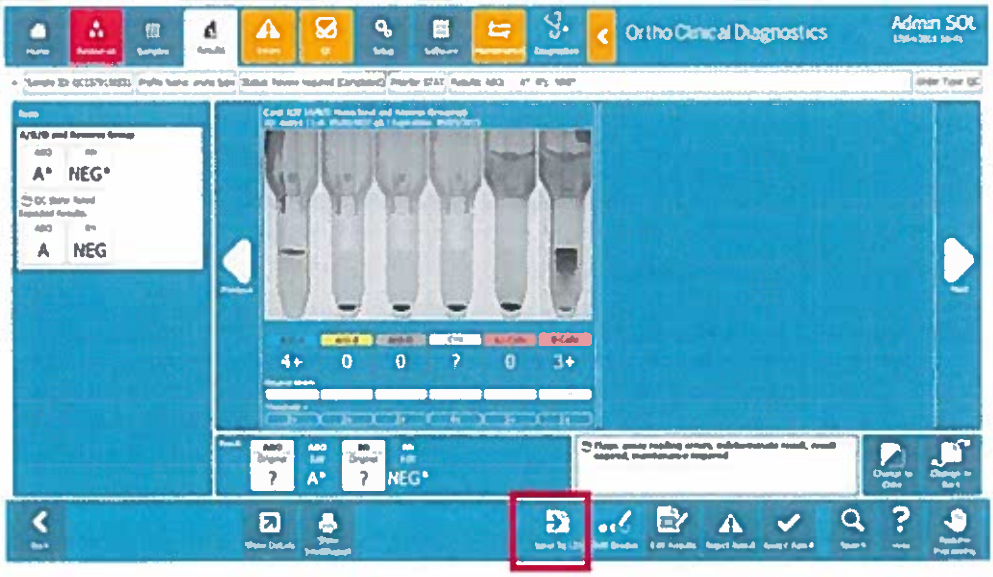
K. **Modify and Accept Results.**

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.



L. **Send Results to LIS.** Manually accepted results must be sent to the LIS.
    1. In the RESULTS SCREEN touch SEND TO LIS.

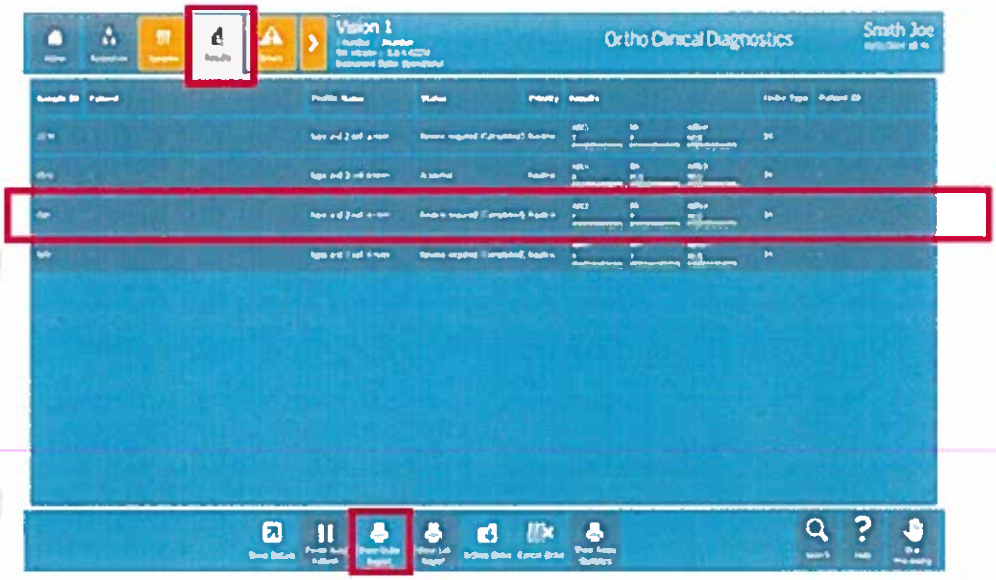


M. **Reject Results.** Rejected results can still be edited or accepted.
    1. Touch the RESULTS menu button.

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_1 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 ≤ 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 **Rh positive.**

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 identifiation 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)

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Applicability

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

Corewell Health East

Transfusion Medicine

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

02/09/2021

Result Code	Definition	Column Interpretation	Conditions	Suggested Actions
U	Unknown	No Result Reported	The system received a result from the IMAGING SYSTEM that was not interpretable.	Rerun the test.
CNF	Column Not Found	If the correct location could not be ensured during the preprocessing check, the column will be marked as not usable; if the correct location could not be found during the post processing check the result is not reported.	The CARD IMAGING SYSTEM could not ensure the column was in the correct location.	If the correct location could not be ensured during the preprocessing check, clean any debris from the surface of the card and load the card into the SUPPLY DRAWER to be reused. If the correct location could not be found during the post processing check, rerun the test.
WLL	Wrong Liquid Level	No Results Reported	The IMAGING SYSTEM could not confirm that the correct volume of liquid is in the reaction chamber. One of the liquid additions may be missing.	Inspect the reaction chamber to determine if the liquid level is correct or not. A false error may be caused by a faint meniscus. If the liquid level is correct, manually read the column and edit the column result. If the liquid level is not correct, inspect the sample and reagents. Remove bubbles or foam before loading tubes and vials onto the instrument. Review the error screen for liquid flow or liquid level errors that are time related and troubleshoot as necessary. Rerun the test. If the error persists, inspect the SYRINGE, DILUTOR VALVE, and TIP TUBING fittings for leaks. Perform the PIPETTE Volume Test to verify metering system integrity.
LTL	Light Too Low	No Result Reported	The light level between the columns is checked with every read; the adjacent light level read was too low. This may be caused when too many red blood cells were pipetted.	There may be debris on the card, or there was not enough sample plasma and red blood cells were aspirated instead of plasma. If there were too many RBCs in the column, they can block light. If the result code is intermittent, there may be debris on the card. Clean the debris from the surface of the cards and rerun the test. Check the sample container and if the plasma has been depleted, rerun the test using a new sample.
LTH	Light Too High	No Result Reported	The light level between the columns is checked with every read; the adjacent light level was too high.	Inspect the card for holes or reflective debris, and rerun the test. If the result code is frequent, the user may need to clean or adjust the IMAGING SYSTEM.
CI	Contrast Interference	No Result Reported	The liquid in the column above the media was dark and the IMAGING SYSTEM could not confidently interpret the reaction. This can be caused by hemolysis, icterus, turbidity or lipemia.	Rerun the test, or manually read the reaction.
Result Code	Definition	Column Interpretation	Conditions	Suggested Actions

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

NC	No Cells	No Result Reported	The IMAGING SYSTEM found that there were no cells or almost no cells in the column.	There may be insufficient reagent or sample volume. Confirm there is reagent and sample available and rerun the test.
TFC	Too Few Cells	No Result Reported	The IMAGING SYSTEM determined that there were not sufficient cells in the column for a valid interpretation.	There may be insufficient reagent or sample volume, or red blood cells may not have been properly suspended. Check the reagent vials and replace them if necessary. Rerun the test.
TMC	Too Many Cells	No Result Reported	The IMAGING SYSTEM determined that there were too many cells in the column for a valid interpretation.	Reagent red blood cells may not have been properly suspended, RBCs may have evaporated, or there was not enough sample plasma and patient RBCs aspirated instead of plasma. If it is suspected that the reagent red blood cells have been compromised due to improper suspension or evaporation discard all vials from that set and replace with a new set. Resuspend the reagents and rerun the test. If the user suspects the sample is the source of the TMC code, make sure there is adequate plasma volume and rerun the test. Recentrifuge the sample if needed.
MF	Mixed Field	No Result Reported	The distribution of the cells within the column indicates that there may be a dual population of cells.	Manually interpret the reaction; follow your laboratory Standard Operating Procedures for dual population reactions.
?	Indeterminate	No Result Reported	The strength of the reaction or the distribution of the cells within the reaction prevented the IMAGING SYSTEM from determining whether the reaction was positive or negative.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures.
FIB	Fibrin	No result reported	The IMAGING SYSTEM saw an agglutinate which may have been caused by fibrin in the sample.	• Manually review the card. • Follow Standard Operating Procedures for the sample for manually reviewing, reporting results and retesting. • Inspect the sample for quality issues. Follow your Standard Operating Procedures for sample processing before testing. • Adjust the centrifugation speed and time to achieve the optimal cell/plasma separation. • If the problem persists, call OCD Customer Technical Support.

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

Result Code	Definition	Column Interpretation	Conditions	Suggested Actions
BUB	Bubble	If a bubble is found during the preprocessing check the column will be marked as not usable; if a bubble is found during the post processing check the result is not reported.	The IMAGAING SYSTEM detected a bubble that was large enough to effect the reaction.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures
FOC	Focus Error	If the focus targets appear to be incorrect in the preprocessing check the card will be marked as not usable; if the focus targets do not look correct during the post processing check the result is not reported.	The focus targets appear to be incorrect to the IMAGING SYSTEM.	Inspect the focus targets for debris and clean them if necessary.
PE	Position Error	No Result Reported	The IMAGAING SYSTEM has determined that the card is not properly positioned.	If the result code is intermittent, rerun the test.
CVE	Column Volume Error	If the liquid volume is inadequate during the preprocessing check the column will be marked as not usable.	The liquid volume above the media is inadequate.	Evaporation of the column liquid may have occurred or the system rejected the card before it was used and automatically ran the test using another card. Refer to the Card IFU to determine proper disposition of the Card.
CND	Card Not Detected	No Result Reported	The IMAGING SYSTEM has determined that the card is not properly positioned or is missing.	If the result code is intermittent, rerun the test.

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

Flags

Results flag information identifies results that are above or below the reportable range. If the result has been flagged, the information listed below is shown:

- Accepted/Rejected
- Transferred to LIS
- Instrument simulated
- Result edited by user

In addition, the flags listed below require a manual review of the result:

- Result expired
- Errors from imaging system
- QC expired
- Lot expiration
- Sensor reading temperature dropping out of the notification range
- Sensor reading humidity dropping out of the notification range
- Maintenance expired/failed
- Edited results

Note: The Suggested Actions described in the preceding table reflects ORTHO VISION™ recommendations. The Blood Bank policies supersede any Ortho recommendations given. Follow department policies when applicable.

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ORTHO VISION™ ANALYZER SYSTEM OVERVIEW

02/09/2021

Introduction

This attachment discusses navigation, features and the functionality of the ORTHO VISION™ Analyzer software. The user interface for the master computer consists of a flat panel monitor with an integrated touch screen. The touch screen is used to access software and navigate through system functions.

Scope

System access is controlled by the access levels configured for each user group that is created on the system. Each user of the ORTHO VISION™ Analyzer is provided a unique user name and assigned to a user group.

Definitions

- **Action Buttons:** Executes actions within the current menu screen. These buttons change according to the menu screen displayed.
- **Assistance Buttons:** The Search, Help, and Stop Processing Action Buttons that are displayed on all screens.
- **Expand Button:** Touch the Expand button to display all of the available Menus. To return to the default view, touch the Expand button again.
- **Indicator:** Displays the current date and time and the user name currently logged into the system.
- **Menu Screen:** Displays the content of the selected Menu and Tools. Use the Menu buttons to change between menu screens.
- **Tools:** Buttons located vertically along the right-side of some menu screens. Use Tools to navigate through screens within the selected menu.

User Login

- Use this procedure to login to the system. If another user is currently logged in, log that user out by touching the Log Out button on the Home screen.
- A valid user name and password are required for this procedure.
- This procedure is located on the Home screen.
    - Touch anywhere on the Home screen to display the User Login screen.
    - Enter your user name and password in the corresponding fields.

  NOTE: These entries are case sensitive.
- Touch ENTER
- The Home screen is displayed with the current logged in user.

User Logout

- Use this procedure to log out of the software as the current user. This procedure is located on the Home screen.
- Touch the HOME menu button.
- Touch the LOG OUT action button.
- No further actions are possible until a new user logs in.
- The system will automatically log out a user after 60 minutes of inactivity.

Home Screen

- The Home screen is the first screen displayed when the system is started.
- Use the Home screen to login, logout, view the Health Check Report, and to shut down the system.
- The Home screen provides an overview of system processes with the Dashboard, which displays current status information for Resources, Samples, Results, and STAT samples.

The Dashboard

The Dashboard provides a status of system processes.
The screen is divided into 4 quadrants that display current system information for Resources, Samples, Results, and STAT samples.

The Resources, Samples, and Results quadrants display a large status indicator that changes color to indicate when user action is required.

Green – Indicates that user action is not required. Samples and Resources are adequate for scheduled testing, manual review is not required, and there are no current warnings or errors.

Orange – Indicates that there is a warning or error that requires user action, but processing continues. A sample may need to be assigned to an order, a resource may be low, or manual review may be required for a result.

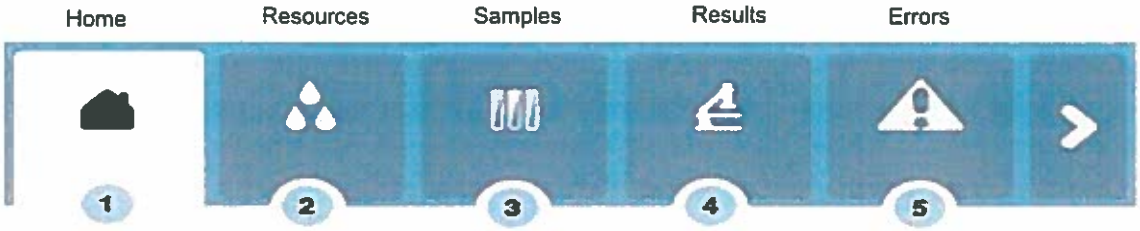
Red – Indicates that there is an error and user action is required now. Processing may have stopped. A sample may have an error, a resource may be depleted, or manual review result may be expired. Red also occurs when the waste or manual load/review drawers are opened.

Menu

ORTHO VISION™ ANALYZER SYSTEM OVERVIEW

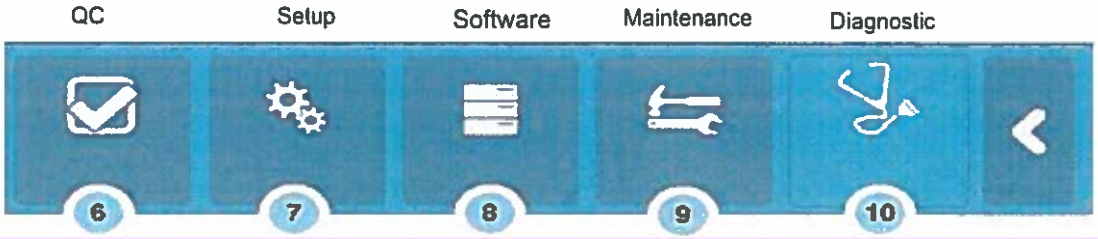
Menu buttons are located horizontally along the top of the user interface and are used to display the different menu screens. The buttons are divided into high-traffic and low-traffic menus.

High-traffic menus include:



Use the Expand button (located next to the Errors menu) to display the low-traffic menu buttons.

Low-traffic menus include:



Menu	Description
1) Home	Displays the Home screen, where you can view the status of system processes on the Dashboard.
2) Resources	Displays the Resources screen, used to manage resources; such as reagents, cards, and diluents.
3) Samples	Displays the Samples screen, used to view, manage and create orders for samples loaded to and registered on the system.
4) Results	Displays the Results screen, used to view, edit, accept, and monitor test results as they are completed.
5) Errors	Displays the Errors screen. Use the Errors screen to view and manage errors that may occur.
6) QC	Displays the QC screen. Use the QC screen to manage QC tasks.
7) Setup	Displays the Setup screen. Use the Setup screen to manage all configurable options for your system. Configurable items include system access, user management, test setups, results, and much more. Limited access to key operators only.
8) Software	Displays the Software screen. Use the Software screen to manage software updates, system backups and Internet connections.
9) Maintenance	Displays the Maintenance screen. Use the Maintenance screen to view and perform required periodic maintenance procedures.
10) Diagnostics	Displays the Diagnostics screen. The Diagnostics screen is not available to customers without a password.

Assistance Buttons

Assistance buttons are the 3 action buttons that remain visible at the bottom right corner of all screens:

Action Button	Description
 **Search**	Opens the Search screen that allows you to search for information in the system databases.
 **Help**	Displays the help screen that contains screen information for the current screen.
 **Stop Processing**	• Stop New Processing — All tests currently in process will be completed. Pending tests will not begin. • Urgent Stop— All tests in process will stop immediately. These tests will be Failed and any results will be lost. Pending tests will not begin.

Resources Overview

Reagents

- The Reagents screen allows you to review current inventory information for the Reagents loaded on the system.
- Touch RESOURCES > REAGENTS to access this screen.
- Use this function to evaluate inventory and manage Reagent Lots
- You can also load and unload Reagents as necessary.
- The action buttons described below are located along the bottom of the Reagents screen:
  - LOAD/UNLOAD: Allows you to place or remove Reagents on or off the system.
  - ASSIGN TO POSITION: allows you to select a position to load reagents

Evaporation Caps

- Evaporation caps are disposable caps the user places on the Reagent Red Blood Cell vial.
- Evaporation caps fit 10 mL vials. The cap is intended to allow access to the probe and prevent evaporation of liquid from the Reagent Red Blood Cell vial.
- Evaporation caps are single use and are only used on Reagent Red Blood Cells.
- All SELECTOGEN® and AFFIRMAGEN® reagents placed on the ORTHO VISION™ must be fitted with evaporation caps.

Reagent Lots

- Touch RESOURCES > REAGENT LOTS to access this screen.
- Use this screen to register lots and view information about reagent kits.

Dilution Trays

- The Dilution Trays screen allows you to view information about the availability and position of dilution wells.
- Touch RESOURCES > DILUTION TRAYS to access this screen.

Dilution Tray Color Indicator

Color	Well Position State	Description
Gray/Blue	Used	Well has been used
Green	Unused	Well has not been used
Blue	Allocated	The well is allocated for processing
Purple	Scanning	It is unsure if the position is free or occupied
Yellow	Warning	Dilution well has a warning
Red	Error	Dilution well has an error

Card Overview

- The Cards screen displays information about the Card carton state and associated information (such as location and Lot expiration dates).
- Use this screen to view the Card type as well as errors and warnings.
- Make sure the foil is sealed properly over all microtubes.
- Touch RESOURCES > CARDS to access this screen.

Partially Used Cards

- A partially used card is a card that contains some punched columns that have been fully processed, and some columns that have not been punched and are available for use.
- Upon receiving an error free result, the card is placed in the room temperature incubator.
- Partially used cards can remain in the room temperature incubator, and be used for additional test processing, for up to 4 hours.
- If a partially used card is not used within 4 hours, or there is no available space in the room temperature incubator; the card is placed in the manual review rack.
- If the manual review rack is full, the card is discarded to the waste drawer.
- Partially used cards are tracked in software inventory but do not appear in card inventory.
- Partially used cards are instrument-dependent, only usable on original testing instrument.
- Partially used cards must be loaded onto the Manual Load/Review rack into the rear 8 input positions.

Waste Overview

- The Waste screen displays the current status of the waste drawer and the liquid waste bottle.
- Touch RESOURCES > WASTE to access this screen.
- Available waste space is displayed in green.
- As the waste containers are filled, the used space displays in orange.
- Touch EMPTY CARDS to access the system and empty the card waste drawer.
- Liquid waste will be maintained only in the Liquid Overview section of this attachment.

- The confirmation dialogue asks you to confirm that card waste container has been emptied.
    - Select YES to confirm. When Yes is selected, the system automatically resets the card waste level. If you select No, the refill level is not reset.

Liquids Overview

- The Liquids screen allows you to monitor the availability of deionized water and saline on the system.
- Touch RESOURCES > LIQUIDS to access this screen.
- The system stores up to 1 liter of deionized water and up to 4.7 liters of saline in separate containers.
- The fill capacity displays on the screen below each container.
- As liquids are used, the remaining liquid level is displayed in green for both containers. The empty level displays in orange.
- Touch REFILL to access the system and empty and refill the liquids.
- The confirmation dialogue asks you to confirm that the liquid waste has been emptied and refilled.
    - Select YES to confirm. When Yes is selected, the system automatically resets the liquid levels to full and liquid waste to empty. If you select No, the refill/empty levels are not reset. Both of these actions must be done together to avoid overflow of waste and system dryout.

Resources Action Buttons

Action Button	Description
 Assign to Position	Displays the Assign to Position wizard.
 Show Details	Displays additional information for the selected item
 Empty Liquid	Starts a wizard which guides you through the process of emptying the liquids container.
 Empty Cards	Starts a wizard which guides you through the process of emptying the Cards container.
 Load / Unload	Starts a wizard which guides you through the process of loading/unloading reagents.

 Refill	Starts a wizard which guides you through the process of refilling the Deionized Water and Saline.

Manual Load / Review Overview

- The Manual Load/Review screen allows you to view the status of tests on the system that require manual review and add low volume cards.
- Touch the RESOURCES > MANUAL LOAD/REVIEW button to access this screen.
- Use the LOAD/UNLOAD button to open the dual purpose drawer to:
  - Access cards for edit.
  - Add low volume, additional, and partially used cards for testing.

Samples Overview

- The Samples screen allows you to review registered samples.
- Use the Samples screen to monitor, register, load and unload samples as needed.
- Samples can be registered in one of two ways:
  - Automatically, through the Laboratory Information System (LIS) and Manually, by physical position.
  - When using barcode labels, it is not necessary to assign the sample to a position on the Samples screen. Place the barcoded sample container in any position on any rack with the label facing out. A scanner reads and decodes the barcode, then transmits the sample ID to the system. The system searches its database to find the corresponding order, or if the system is configured for Host Query, it will request the order from the Laboratory Information System (LIS).

Samples Action Buttons

Action Button	Description
 Load / Unload	Use this screen to open the LOAD STATION DOOR in order to load and unload samples on the system.
 Assign to Position	Use this screen to select a position to assign a sample to.
 Create Order	Use this screen to manually create an order.
 Modify Order	Use this screen to select an order and make modifications to that order.
 Show Details	Displays additional information for the selected item.
 Batch Order	Use this screen to select multiple samples for an order.
 Cancel Order	When an order is canceled, test processes are stopped.
 Add Donor Sample	Displays a field to enter Donor ID's when creating an order for crossmatch tests.
 Cancel	Closes the screen and does not save entered data.
 Save and Start	Saves the entries or changes made on the screen and starts the order.

ORTHO VISION™ ANALYZER SYSTEM OVERVIEW

Sample Racks

Patient Sample Racks

- 10 mm diameter (RED, labeled S10B)
- 13 mm diameter (BLUE, labeled S13B)
- 13 mm diameter with extenders (BLUE, used with microtainers)

Rack Color	Sample Tube Used	Notes
Red	10 x 75 mm glass tubes	• Confirmatory type of Donor units • Donor units for XM
Blue	13 mm pink top (BB) 13 mm purple top (CBC)	• All Patient testing
Gray	Diluent Rack	The DILUENT RACK supports two 10 mL vials and two 100 mL bottles.
White (11 spaces)	Reagent Red Cell Rack for Panel A and B	The 3 mL Reagent Red Cell Rack has a capacity for eleven 3 mL vials and caps. Caps are stored directly below the corresponding vial.
White (6 spaces)	Reagent Red Cell Rack for Selectogen® and Affirmagen®	The 10 mL Reagent Red Cell Rack has a capacity for six 10 mL vials and caps. Caps are stored directly below the corresponding vial.

Results Overview

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. Touch the Results button to access this screen.

Results Action Buttons

Action Button	Description
 Accept Results	Accepts the selected test. *Note: After a result is accepted, the Accept Result button is disabled and the result can no longer be edited.*
 Archive Order	Archives a canceled or reviewed order.

ORTHO VISION™ ANALYZER SYSTEM OVERVIEW

 Cancel Order	Cancels an order in process or an order that has not been started.
 Edit Grades	Starts a wizard which guides you through the process of editing the column grade. *Note: The Edit Grades button is active if all test analysis results are available and the test has not been accepted.*
 Edit Results	Starts a wizard which guides you through the process of editing the final interpretation.
 Show Details	Displays additional information for the selected item.
 Show Order Report	Displays the Order Report.
 Send to LIS	Sends all accepted results of the related profile to LIS.

Note
All results that require manual review must be interpreted from the MTS® ID Card NOT from the image on the ORTHO VISION™ screen.

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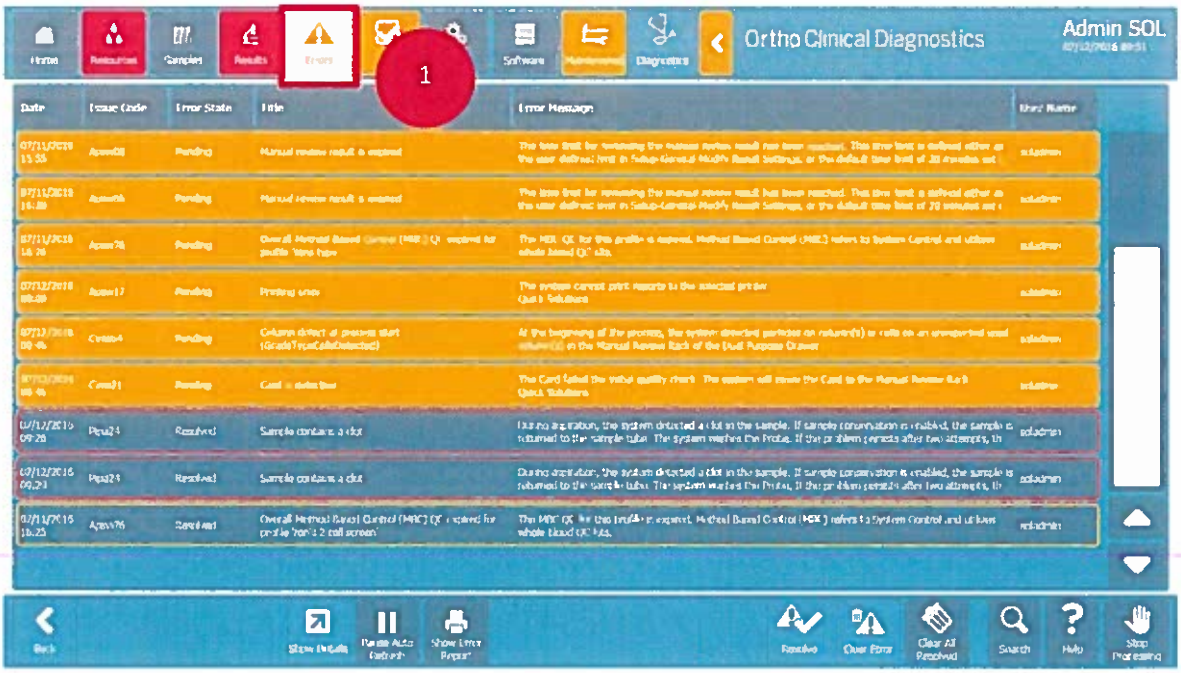
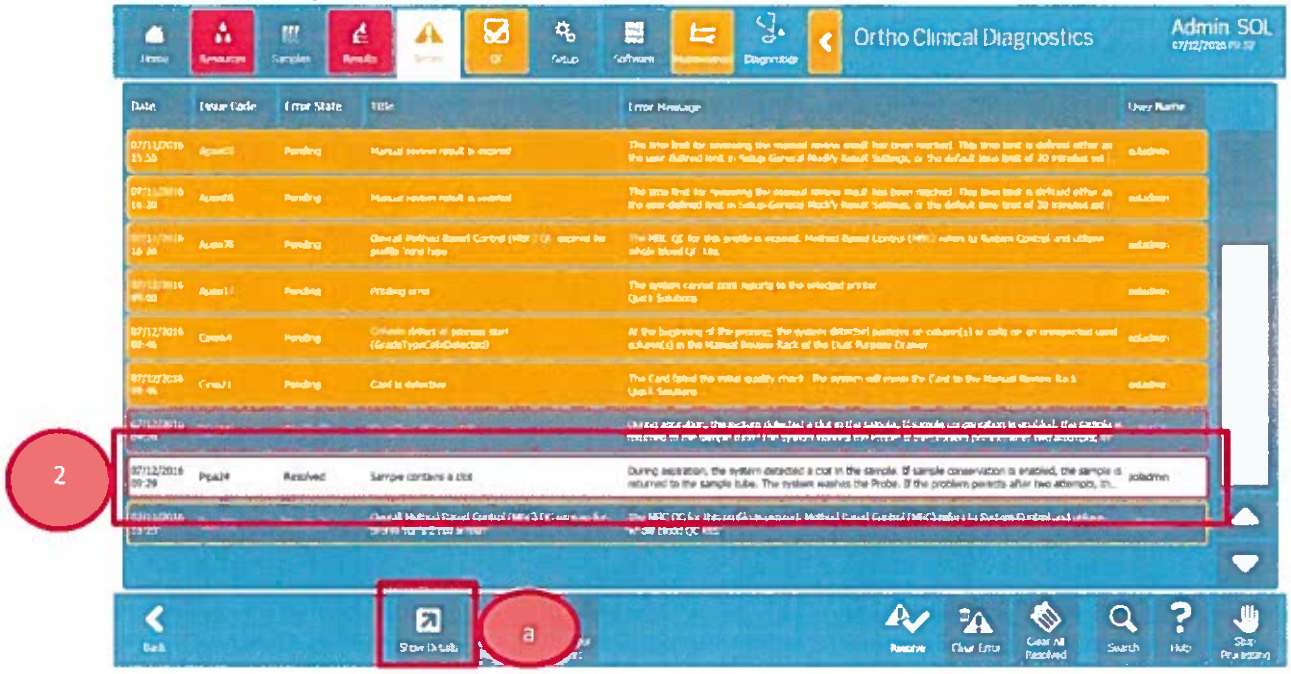
ORTHO VISION™ ERROR HANDLING

02/09/2021

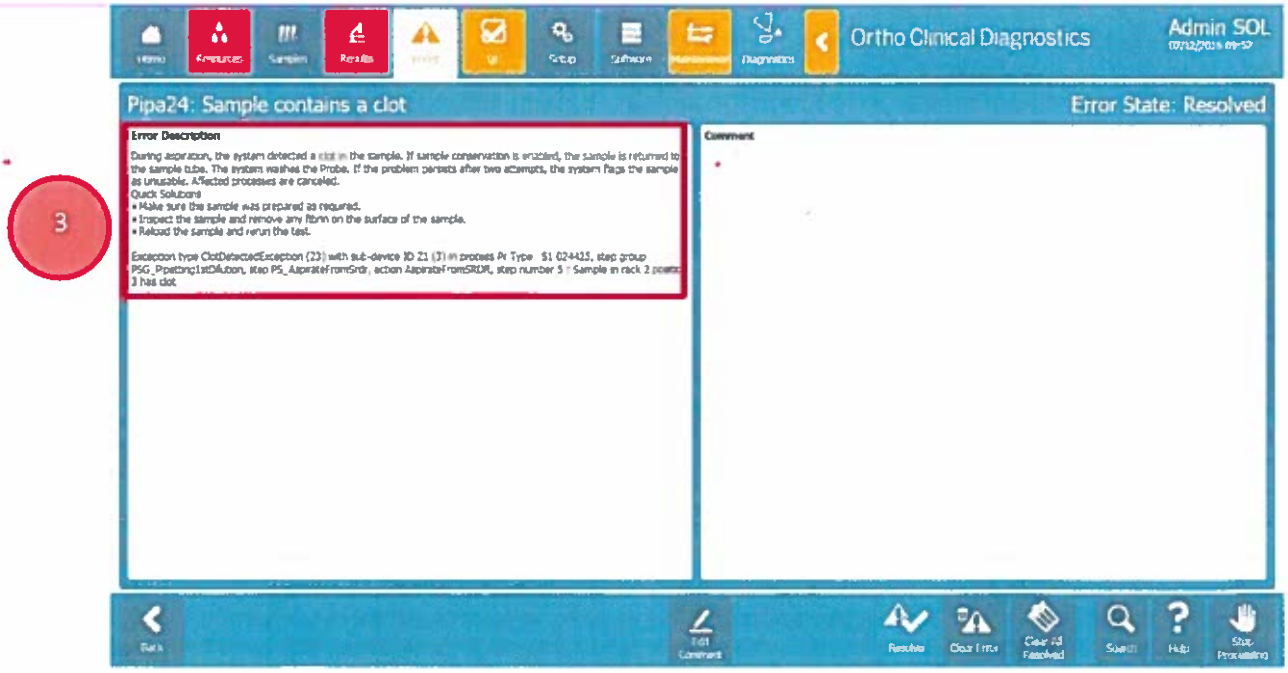
1. Touch ERROR Menu – this will be color coded according to the level of severity.
    a. Errors are sorted by DATE/ERROR CODE/ERROR STATE, etc. - with the latest error at the top.



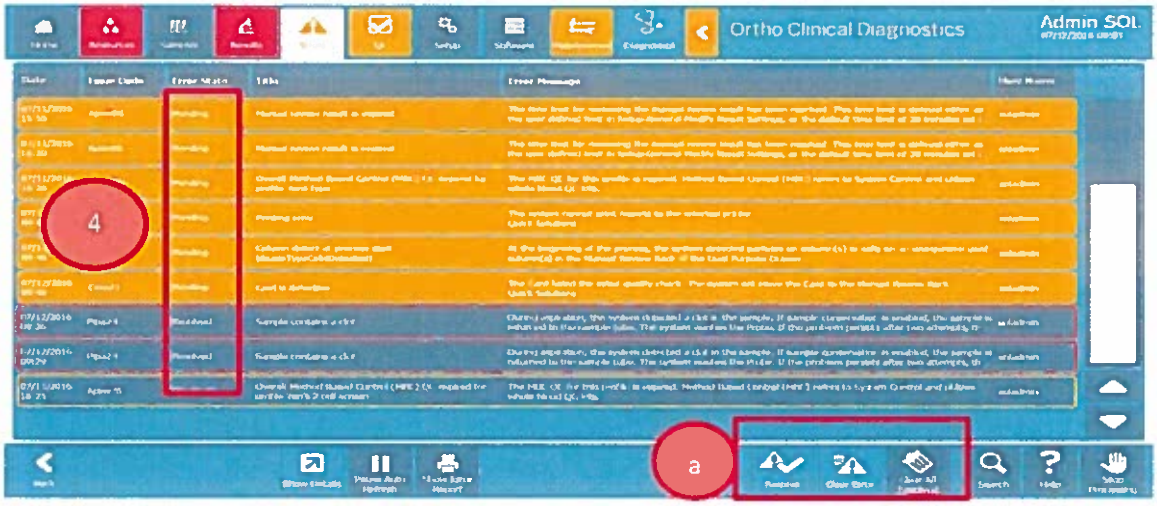
2. Select the Error you wish to view.



3. Read the Error Description and Quick solutions in order to resolve.



4. If the Error is showing as pending, and you have addressed, you will need to highlight the Error and touch Resolve.
    a. To clear resolved errors from the screen, highlight the error and touch Clear Error or Clear all Resolved.



5. There is also an option to Edit Comment to an Error Description- this comment will always show with the error.