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AUTHOR: G938509	**PREVIOUS NUMBER:**
OWNER: G938509	**CHANGE NUMBER:** SCPMG-CR-0656

Routine Testing and Result Management, Ortho Vision™ Analyzer

Purpose

This document provides guidelines for routine testing of patient and donor samples on the Ortho Vision™ Analyzer and management of test results.

Policy

- Automated testing for patients and donors using the Ortho Vision Analyzer is the preferred method for testing in the SCAL Transfusion Services.
    - When the analyzer is determined to be not suitable for performing testing (malfunction, quality control failure etc.) manual gel and/or manual tube methods are considered the backup methodologies.
- A bi-directional interface is utilized to download patient test requests and upload the results to the laboratory information system (LIS).
    - If the LIS interface is not functional a manual test request can be inputted into the analyzer.
- Testing Profiles are set per regional specifications and require a local variance for any changes from the regional specifications document.
    - All samples tested which do not have negative control (ie Type AB or AB Pos) will have a control well run. This is a reflex test on the analyzer, it is the responsibility of the CLS to ensure that the control well is tested and has the expected result (negative).

Limitations

Ortho Vision™ Analyzer Limitations:

- The analyzer is not designed to automatically report hemolysis as a final result; however, a 'CI' microtube result will be reported for a microtube that cannot be appropriately graded as a result of contrast interference (CI), which is often caused by hemolysis.
    - The user, upon manual review of the result, can enter a comment of hemolysis, if hemolysis is observed.
- Antigen typing tests with mixed field will be resulted as mixed field 'MF', requiring users to determine the appropriate grading based on patient history and clinical information.

See Ortho powerpoint I sent on MF rxns

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Limitations Con't

- RhD antigen testing in ID-MTS™ Gel Cards containing Anti-D is performed by direct agglutination; therefore, very weak expressions of D may not be detected and may require the use of a validated antiglobulin test for detection.
- When a sample is collected from a recently transfused patient, the potential exists for the transfused red cells to concentrate after centrifugation at the bottom of the sample tube below their autologous cells. The probe aspirates from the bottom of the tube where the transfused cells generally concentrate which may lead to an unexpected result.

MF

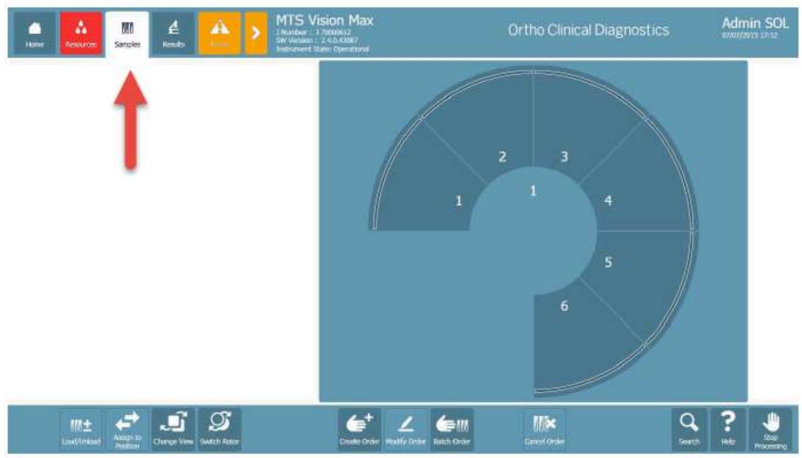
- A sample with a very high-titer antibody (>1:1024) when tested for antibody screening may intermittently cause carry-over in the next pipetted sample.
  - Carry-over was not observed in samples with antibody titers of 1:512 or 1:1024 under normal operating conditions.

ID-MTS™ Gel card Limitations:

- Anomalous results may be caused by fresh serum, fibrin, or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube.
- Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution.
- Rouleaux caused by serum or plasma with abnormally high concentrations of protein may infrequently cause difficulties in test interpretation. False positive results or hazy reactions may occur with these samples but are rare.
- See Instructions for Use for addition information regarding Limitations of specified gel card.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure

Loading Sample with Interfaced Orders from LIS	
Step	**Action**
1.	Touch Samples > then select a ring position into which you want to load samples.  Select any additional ring positions into which you want to load samples (you may select all six).
2.	Load the samples into the rack(s) • Verify the caps have been removed from the samples. • Place the uncapped samples in the rack(s) with the barcode facing out. Place the rack(s) in the Load Station and close the door.

3.	The analyzer will perform an inventory and post the samples.
	• For patient samples the analyzer will query the LIS and download the associated tests requested from the LIS.
	  ○ ABO/Rh
	  ○ Antibody Screen
	  ○ Cord Blood ABD
	  ○ DAT(IgG)
	  ○ ABORh Dbl Ck
	  ○ ABORh Baby
	
	Other patient tests (XM IAT, Antibody ID, Ag typing) and all donor unit confirmation tests are not interfaced tests and are required to be manually ordered on the analyzer. See section below.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

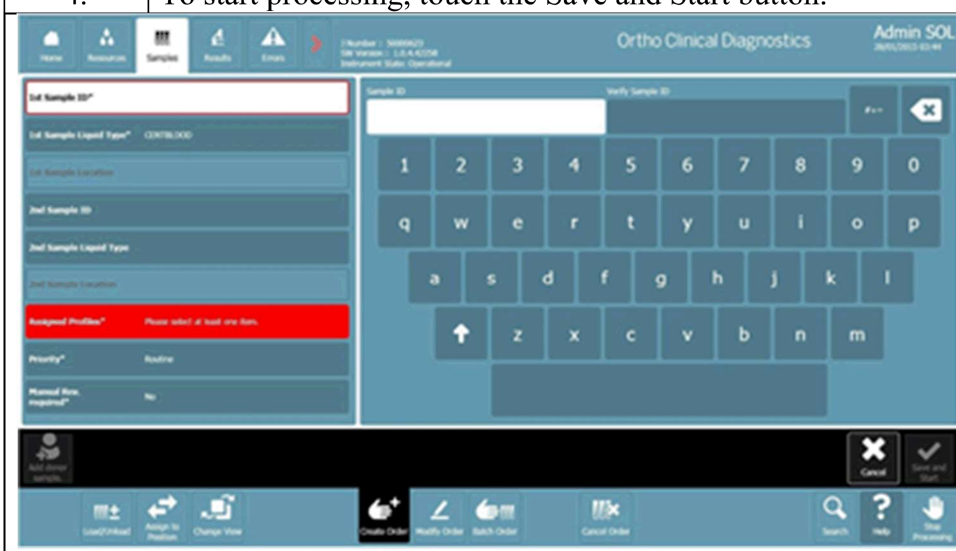
Procedure

Loading Sample with Non-Interfaced Orders from LIS

Step	Action
1.	Touch Samples > select sample.
2.	Touch Create Order.

3.	Fill in the required details:
	• Sample ID (if sample was not selected on previous screen)
	    ○ For non-barcoded samples, manually type in twice for the double blind sample ID entry.
	    ○ For barcoded samples, scan the tube with the handheld barcode scanner into the required fields.
	• Test profiles to be run
	    ○ Antibody ID (For selected cell panels see below)
	    ○ UC O POS
	    ○ UC Rh Neg
	    ○ UC A, B & AB POS
	• Priority and whether a manual review is required.
	NOTE: For the XM IAT see below.

4.	To start processing, touch the Save and Start button.



Testing is initiated on samples when all test conditions and system requirements are met.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure

Loading Samples with Non-Interfaced Orders from LIS-Batch Order	
Step	**Action**
1.	Touch Samples > Create Batch
2.	Touch Sample ID and select the samples to include.
3.	Fill in the required details: • Test profiles to be run • Priority and whether a manual review is required.
4.	To start processing, touch the Save and Start button.

Procedure

Program Crossmatch testing (XM IAT)	
Step	**Action**
1.	Touch Samples > Create Order
2.	Touch Sample ID and select the sample ID for the recipient.
3.	Select the test profile XM IAT • Fill in additional details such as fluid type.
4.	Touch Add Donor Sample once for each donor sample and fill in required fields.
5.	Touch Save and Start
6	Load samples into the Load Station

Procedure

Program Selected Cell Panels	
Step	**Action**
1.	Touch Samples > (select sample) Touch Create Order
2.	Fill in the required details: • Sample ID (if sample was not selected on previous screen).
3.	Touch Assign Profiles, choose panel with selected cells to be tested.
4.	Touch Disable Assays.
5.	Touch Panel Cells that are NOT being tested, Panel cells that are being tested should be in White.
6	Touch Save and Start.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure

Viewing Results

Step	Action
1.	Touch the Results menu button to view active orders and to access the results of completed tests.  To view images of the completed test: • Touch the result you want to view • Touch the Show Details button. The image and graded result will display on the screen.
2.	From this screen in Step 1 select: • Accept or reject the result. • Change the type of image viewed (front or back, color or grayscale). • Edit the column grade or result • Enter comment when editing a result grade • Reviewed, accepted results should automatically archive
3.	To review indeterminate results or other results flagged for manual review: • Touch Resources>Manual Load/Review • Use the Load/Unload button to retrieve cards from the Dual Purpose Drawer.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure Con't

Viewing Results	
Step	**Action**
4.	**To Change Card View** View either side of tested cards. • Touch the Results menu button • Select a result and touch the Show Details action button. The Show Details screen is displayed with an image of the card. • Touch the Change to Back action button. o The reverse side of the card is displayed and the button becomes Change to Front.
5.	**Change Image to Color or Grayscale** The card imaged can be viewed in color or in grayscale. • Touch the Results menu button. • Select a result and touch the Show Details action button. • Touch the Change to Color button. The color image is displayed, and the button becomes Change to Grayscale.
6	**Zoom the Image** Enlarged column images can be viewed in the Results— Details screen. • Touch the Results menu button. • Select a result and touch the Show Details action button. The Details screen is displayed with an image of the card. • Touch the column you wish to see enlarged. • An enlarged view of the column is displayed in color and in grayscale. This view also shows both the front and back sides of the column. • Touch Back to return to the Details view.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure

Edit a Column Grade	
Step	**Action**
1.	Touch the Results menu button.
2.	Select a sample ID and touch the Show Details action button.
3.	Touch the Edit Grades action button.
4.	A wizard opens, complete the following: Select the card with the grade you wish to edit. • If scanning the barcode is required, scan the barcode for the card. • If scanning the barcode is not required, and there is more than one card for this test, select the image of the card from those displayed. • If scanning the barcode is not required, and there is only one card for this test, this step is omitted.
5.	Touch the grade for the column you wish to edit. • Alternative grades are displayed. • Select the grade you want for that column. • An asterisk indicated the edit.
6.	Touch Next to add a comment. • Comment “VI OK” to document Visual Inspection OK • Add additional comments as needed (dual population, etc.)
7.	Touch Next and enter your password and touch Confirm Password.

Procedure

Edit Results-Restricted to Key Operator	
Step	**Action**
1.	Touch the Results menu button.
2.	Select the results you wish to edit and touch the Show Details action button.
3.	Touch the Edit Results action button.
4.	A three-screen wizard opens., complete the following: • Select the result you wish to edit, select a new result and touch Next. • Enter a comment describing your change and touch Next. • Enter your password and touch Confirm Password.
5.	The edit is reflected in the Results—Details screen, marked with an asterisk indicating a modified result.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure

Adding comment, accept, reject results

Step	Action
1.	**Adding a Comment to a Result** • Touch the Results menu button and select a result. • Touch Show Details. The card image appears. • Touch Show Details again, and then touch Add Comment. • Enter your comment and touch Save
2.	**Accept Results** Results requiring manual review must be accepted or rejected. Only accepted results can be sent to the LIS. • Touch the Results menu button, select a result. Review the result prior to accepting. • Select a result and touch the Show Details action button. • Touch the Accept Result action button. When a result has been accepted, the status will change to “Accepted” in the status a window on the Details screen. Note: Accepted results cannot be edited.
3.	**Reject Results** Results that are not automatically accepted must be reviewed before they can be accepted or rejected. • Touch the Results menu button. • Touch a row to select a test. • Touch the Show Details action button. Review the results before rejecting the result. • Touch the Reject Result action button The “Rejected Result” icon appears next to this result on the Details screen. Rejected results can still be edited or accepted.

Routine Testing and Result Management, Ortho Vision Analyzer, Continued

Procedure

Search, Print, and Send Result to the LIS	
Step	**Action**
1.	**Search Results** • Touch the Results menu button. • Touch Search. • Enter the search term and touch Search. Some examples of search terms you can enter include: Patient ID, Sample ID, Profile name, etc. The items matching your search are displayed. • Touch the Results link to access that information. • Touch New Search icon to repeat the operation with new search term. • Touch Close Action button to exit from Search function.
2.	**Print a Result Report** • Touch the Show Order Report button. • The report is displayed, and the Print button becomes available. • Touch the Print button • A printed copy of the report is generated.
3.	**Send Results to the LIS** Results must be accepted before you can send them to the LIS. • Touch the Results menu button. • Select a result and touch the Show Details action button. • Touch the Send to LIS action button.