1.0 Purpose

This document provides instruction on viewing, accepting, modifying results as well as canceling pending orders, searching for results, and printing sample test reports. This document also provides instruction on management of test samples with error codes and indeterminate result flags.

1.1 Principle

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

2.0 Scope

Blood Bank CLS that have been trained and deemed competent for operation of the Vision analyzer including this procedure.

3.0 Materials

Safety Precautions

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

Specimen

a.	Centrifuged whole blood pink top EDTA anticoagulated samples.
b.	Anticoagulated donor unit packed red cells.

Equipment Calibration and Maintenance

a.	All scheduled Vision preventative maintenance performed successfully to current date.

Supplies

a.	Ortho Vision liquid and gel card reagents and sample dilution wells as referenced in the **Ortho Vision Routine Testing** SOP.
b.	Ortho MTS gel cards and traditional reagents for manual testing and serological problem resolution.

4.0 Quality Control

a.	Daily QC has been successfully completed, reviewed and accepted by performing CLS.
b.	As needed Vision QC for Rh Phenotype successfully completed on the day of use.

5.0 Procedure

Step	Action
1.	To view active orders and to access the results of completed tests, touch the **Results menu button.**

2.	**Sort Results as listed on the Results menu** 1. This procedure is performed from the Results screen. 2. Touch the Results menu button. 3. Touch a column heading to sort the information in that column alpha-numerically. • All other information is sorted accordingly. 4. Touching a row the second time reverses the sort order. 5. Touch Help for more information.
3.	**Review Completed Tests** To view images of the completed test, touch the result you want to view, and then touch the **Show Details** button. The image and graded result will display on the screen. From this screen you can: 1. Accept or reject the result. 2. Change the type of image viewed (front or back, color or gray scale). 3. Edit the column grade. 4. Enter comment when editing a column grade. 5. Save and print reports. 6. Archive a result
4.	**Manually review results when a test has been flagged for manual review.** 1. The **Manual Load/Review** screen displays the status of tests on the system that require manual review. 2. To access the Manual Load/Review screen and retrieve cards: a. Touch the **Resources > Manual Load/Review**. b. Touch the Load/Unload button and retrieve cards from the Dual Purpose Drawer 3. Perform a visual review of the card and scan the card barcode.
5.	**Change Card View** You can view either side of tested cards. This procedure is performed from the Results > Show Details screen. 1. Touch the **Results** menu button. 2. Select a result and touch the **Show Details** action button. 3. Show Details screen is displayed with an image of the card. 4. Touch the **Change to Back** action button. **5.** The reverse side of the card is displayed, and the button becomes **Change to Front.** 6. Touch Help for more information.

Step	Action
6.	**Change Image from Color to Grayscale** You can view the card image in color or in grayscale. This procedure is performed from the Results > Show Details screen. 1. Touch the Results menu button. 2. Select a result and touch the Show Details action button. 3. Touch the Change to Color button. • The color image is displayed, and the button becomes Change to Grayscale. 4. Touch Help for more information.

7.	**Zoom the Image** You can view enlarged column images in the Results > Show Details screen. 1. Touch the Results menu button. 2. Select a result and touch the Show Details action button. 3. The Details screen is displayed with an image of the card. 4. Touch the column you wish to see enlarged. 5. 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. 6. Touch Back to return to the Details view. 7. Touch Help for more information.
8.	**Edit a Column Grade** The Edit Grades action button is enabled if all test analysis results are available and the test has not yet been accepted. This procedure is located in Results. 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. 5. Select the card with the grade you wish to edit. a. If scanning the barcode is required, scan the barcode for the card. b. 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. c. If scanning the barcode is not required, and there is only one card for this test, this step is omitted. 6. Touch the grade for the column you wish to edit. 7. Alternative grades are displayed. 8. Select the grade you want for that column. • The grade you selected now appears as the grade for that column. An asterisk (*) indicates the edit. 9. Touch Next to add a comment describing the reason for the change. 10. Touch Next and enter your password and touch Confirm Password. 11. Touch Help for more information.
9.	**Adding a comment.** You can add a comment to a result. 1. Touch the Results menu button and select a result. 2. Touch Show Details. The card image appears. 3. Touch Show Details again, and then touch Add Comment. 4. Enter your comment and touch Save.

10.	**Accept Results** Results requiring manual review must be accepted or rejected. Only accepted results can be sent to the LIS. This procedure is performed from the Results menu. 1. Touch the Results menu button and select a result. 2. Touch the Show Details action button. Review the result prior to accepting. **3. If there are no flags, error codes, questionable grades or indeterminate / discrepant interpretation, proceed to accept the result.** 4. Touch the Accept Result action button. 5. When a result has been accepted, the status will change to “Accepted” in the status window on the Details screen **Note:** Accepted results cannot be edited. 6. Touch Send to LIS for results that are interfaced e.g. ABORh, ABSC, Cord, Unit Confirmation. 7. Help for more information.
11.	**Reject Results** Results that are not automatically accepted must be reviewed before they can be accepted or rejected. This procedure is performed from the Results menu. 1. Touch the Results menu button and select a result. 2. Touch the Show Details action button. Review the results before rejecting the result. **3. If the result cannot be resolved to an acceptable result by visual inspection and modification to clear cut column reaction grades, the result must be rejected and the sample must be moved to the manual bench for a discrepancy work up.** 4. **If reaction results are flagged at or below minimum accepted thresholds per protocol, the result must be rejected and the sample moved to the manual bench for further investigation.** 5. Touch the Reject Result action button 6. The “Rejected Result” icon appears next to this result on the Details screen. Rejected results can still be edited or accepted. 7. Touch Show Order Report and print. 8. Touch Help for more information.
12.	**Print a report.** 1. The Print button is available whenever a report is displayed and a printer is configured. “Show Report” buttons appear throughout the software. 2. Touch a Show Order Report button. 3. The report is displayed, and the Print button becomes available. 4. Touch the Print button. 5. A printed copy of the report is generated. 6. Touch Help for more information

13.	**Search Results** Use this procedure to search for Results information. 1. Touch the Results menu button. 2. Touch Search. 3. Enter the search term and touch Search. Some examples of search terms you can enter include: Patient ID, Sample ID, Profile name, etc. 4. The items matching your search are displayed. 5. Touch the Results link to access that information. 6. Touch New Search icon to repeat the operation with new search term. 7. Touch Close Action button to exit from Search function. 8. Touch Help for more information.
14.	**Send Results to Cerner Millennium** Results must be accepted before you can send them to the LIS. This procedure can be performed from Results menu. 1. Touch the Results menu button. 2. Select a result and touch the Show Details action button. 3. Touch the Send to LIS action button. 4. Touch Help for more information.
15.	**Archiving Results** 1. To archive a result, select it and touch the Archive Order button. 2. The Vision has been configured to automatically archive completed orders after 4 hours. Completed status consists of Accepted, Rejected, Cancelled, or Aborted. 3. Orders which are pending, non-running and incomplete will auto archive after 8 hours. 4. Once a result has been archived, it will no longer appear on the Results screen, and it will no longer be possible to create the Order Report for it.

6.0 Limitations

6.1	**Limitations**

	Refer to Table 1 below for Error Codes/Flags that will require repeat testing and Error Codes/Flags that may be edited.

6.2	**Result Positive Thresholds**

	The following reaction grades have been configured as questionable and cards with these results or lower will be forwarded to the manual review rack. Follow manual bench procedures for investigation and resolution.

Test Profile	Thresholds Grades
ABO forward	2+
ABO reverse	1+
Ctrl	4+

	Rh-D (including weak D And D IV) 2+ Phenotype 2+ IAT / DAT /Ident / XM 1+

7.0 Corrective Action

7.1	**QC Out of Acceptable Range**

a.	Patient results cannot be reported if QC does not meet acceptable criteria. QC that is run with patient testing must be repeated and successful before patient results can be reported.
b.	Investigate QC failure: review QC sample preparation, check reagents and gel cards for expiration date and for signs of contamination, and verify appropriate barcode labels.
c.	Refer to **Ortho Vision Quality Control** SOP for additional instructions.

7.2	**Instrument Warning or Error Codes and Flags**

	Error Codes 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. The table below displays Result Values. Result Values are shown on the Results screen, printed on reports, and included on Log files. If a result code is frequent, contact Customer Technical Support. Always refer to the Instructions for Use and the Reference Guide for additional information. **See Table 1 Flags and Error 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/failed • Lot expired • Sensor reading temperature dropping out of the notification range • Sensor reading humidity dropping out of the notification range • Maintenance expired/failed • Edited results

7.3	**Instrument Downtime Action Plan - Alternate Test Method**

	If the Vision is non-operational, the alternate method for Type & Screen is manual tube ABORh and manual Gel ABSC, for Cord DAT IgG is manual tube DAT IgG, for Crossmatch IAT and panel workup is manual Gel, for Unit Confirmation is manual tube.

8.0 Documents and Records

8.1	Any test results that are not interfaced or are not sent electronically from the analyzer must have the Order Report printed. Upon manually entering the results, a 2nd CLS will need to verify that the computer entry is correct and accurate.
8.2	Any patient results that require Editing of Column Grades must have an Order Report printed and a 2nd CLS review to verify correct and accurate edits.

9.0 Related Documents

9.1	ORTHO Vision® Analyzer Quick Reference Guide, current revision.
9.2	ORTHO Vision® Analyzer ID-MTS® Gel Cards Reference Guide, current revision.
9.3	ORTHO Vision® Analyzer ID-MTS® Gel Cards Self-Service Customer Procedures Guide, current revision.

9.4	**Performing ABO Grouping & Investigating ABO Grouping Discrepancies** SOP
9.5	**Rho(D) Typing** SOP

Table 1. Flags and Error Codes

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
0	N/A	Negative	N/A	Refer to **Performing ABO Grouping & Investigating ABO Grouping Discrepancies** and **Rho(D) Typing** SOPs for minimum acceptable threshold grades.
1+	N/A	Positive	N/A	
2+	N/A	Positive	N/A	
3+	N/A	Positive	N/A	
4+	N/A	Positive	N/A	
U	Unknown	No Result Reported	The system received a result from the IMAGING SYSTEM that was not interpretable.	Repeat 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, manually read the reaction.
WLL	Wrong Liquid Level	No Result 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.	Repeat the test. Inspect the reaction chamber to determine if the liquid level is correct. 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 analyzer. Review the error screen for liquid flow or liquid level errors that are time related and troubleshoot as necessary. Repeat 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.

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
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 card and perform a manual read of the column. Check the sample container and if the plasma has been depleted, repeat 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 manually read the reaction. 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.	Manually read the reaction if the column reaction is clearly evident. Request redraw for hemolyzed samples.
NC	No Cells	No Result Reported	The IMAGING SYSTEM found that there were no cells or almost no cells in the column.	Repeat the test. There may be insufficient reagent or sample volume. Confirm there is adequate 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.	Repeat the test. 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.	Repeat the test. 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. Re-centrifuge 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.	Repeat the test by manual methods.
?	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.	Repeat the test or manually read the reaction if the column reaction is clearly evident.

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
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. Inspect the sample for quality issues. Rim sample and re-centrifuge. Repeat the test. If the problem persists, call OCD Customer Technical Support.
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.	Manually review the card. Repeat the test.
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.	Repeat 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, repeat the test.