University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 06-20-2019 Revision Effective Date:	Number: PC-0074.01

TITLE: **Ortho Vision® General Operation**

PURPOSE:
To provide instructions for general operation of the Ortho Vision®

PRINCIPLE & CLINICAL SIGNIFICANCE:
Improper handling of instrument, reagents and MTS cards can interfere with the accuracy of test results and cause errors and/or failure of the test system with the potential to delay the availability of results or produce erroneous test results and FDA reportable events. The Ortho Vision™ analyser is an instrument designed to automate in vitro immunohematology testing of human blood utilizing the ID-MTS™ gel card technology. Ortho Vision® analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, recation grading and interpretation and data managements requirements using cards and digital image processing.

POLICIES:
- The Ortho Vision® will be operated according to manufacturer instruction and UWMC TSL policies and procedures.
- Only qualified and trained laboratory personnel are allowed to use the system.
- Quality control must be performed and acceptable prior to reporting patient and blood component test results
- The supply drawer is not intended for reagent or diluent storage. Refer to SOP: *OrthoVision® Resource Management and Daily Quality Control* for storage specifications.
    - Agitated and non-agitated reagents must be loaded in the appropriate locations on the rotor to ensuring reagents remain suspended in solution

REAGENT	LOCATION
Agitated	Inner Rotor
Non-agitated	Outer Rotor

- The following instructions cover most normal operations of the Ortho Vision® analyzer. The user should refer to the Appendices for specific system overview and status indicators. The manufacturer's operation and service manuals should be consulted for events and issues not covered by this procedure.

SPECIMEN REQUIREMENTS: N/A

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
• ID-MTS™ Diluent 2 Plus • ID-MTS™ Diluent 2 • ID-MTS™ Gel Cards • 0.8% AFFIRMAGEN®	• Evaporation Caps • Dilution Trays • Reagent Racks	• ORTHO VISION®

Reagents:	Supplies:	Equipment:
Reagent Red Blood Cells • 0.8% SURGISCREEN® Reagent Red Blood Cells • 0.8% ORTHO RESOLVE® Panel Reagent Red Blood Cells • DI Water • Blood Bank Saline		

QUALITY CONTROL:
Quality Control is performed daily
Refer to SOP: *OrthoVision® Resource Management and Daily Quality Control*

INSTRUCTIONS:

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Power-on and Start Up

STEP	ACTION
1	Verify the power cable is plugged into an appropriate electrical outlet (red outlet)

STEP	ACTION
2	Press the power on switch on the right side of the analyzer to the on position **NOTE:** The system automatically runs a diagnostic analysis. This will take approximately 19 seconds.
3	Enter your 'Login' and password when diagnositics are complete and the Home Dashboard is displayed. **NOTE:** Any samples found on board the system at startup will be marked as expired. Any liquid reagents in the agitated supply at startup will be marked as requiring agitation.

Shutdown

STEP	ACTION
1	Touch <Home>
2	Touch <Shut Down> action button **NOTE:** A confirmation screen will display
3	Touch <Yes> to confirm. Shutdown processing begins
4	Wait for the following to occur: • Green light under the monitor is blinking • "No Signal Detected" message is displayed
5	Power off system by pressing the power switch on the right side of the instrument.

Emergency Shutdown

IMPORTANT: Emergency shutdown should only be performed if normal shutdown procedures are not available.

STEP	ACTION
1	Touch <Stop Processing>
2	Touch <Perform Urgent Stop>

User Login and Logout

STEP	ACTION
1	Touch anywhere on the Home screen to display the User Login screen **NOTE**: The current logged in user is displayed on the Home screen.
2	Enter your user name and password in the corresponding fields
3	Touch <Enter>

STEP	ACTION
4	Touch <Log Out> action button

Loading and Unloading Reagents Overview

STEP	ACTION
1	Touch <Resources>
2	Touch <Reagents> to access the reagent screen
3	Touch <Show Details> while in table view of the Resources screen to access the Load/Unload button
4	Go to the section

If	Go to Section
Loading 0.8% AFFIRMAGEN® and/or 0.8% SURGISCREEN® Cells	**Loading 0.8% AFFIRMAGEN® and 0.8% SURGISCREEN® Reagent Red Blood Cells**
Loading 0.8% ORTHO RESOLVE® Panel Cells	**Loading 0.8% ORTHO RESOLVE® Panel Reagent Red Blood Cells**
Unloading red blood cell reagents	**Unloading Reagent, Diluents and Dilution Trays**

Loading 0.8% AFFIRMAGEN® and 0.8% SURGISCREEN® Reagent Red Blood Cells

STEP	ACTION
1	Allow reagent red cells to come to room temperature
2	Gently resuspend reagent red cells, avoid creating bubbles or foam
3	Label bottles with open date, tech ID, 5-day expiration date, or original manufacturer's date if shorter
4	Remove red caps and place them on the reagent rack cap holder below their corresponding bottle. **NOTE:** Alternatively, caps may be labeled to avoid contamination
5	Place evaporation caps on reagent red cells bottles and load onto the reagent rack labeled R10B with barcode labels facing out
6	Touch <Resources> on the home screen
7	Touch < Reagents>
8	Touch the rack position to be loaded **NOTE:** Reagent red cells can go in positions 1, 2, 3
9	Touch < Load/Unload>

STEP	ACTION
10	Open the door when unlocked and load reagents onto the selected postion **NOTE:** The instrument will run an inventory of reagents and post them in green when ready to use
11	**If reagents are** / **Then** Posted in green / Go to next step Not read by analyzer / Go to secton **Manual Assignment of Reagents**
12	Close load station door

Loading 0.8% ORTHO RESOLVE® Panel Reagent Red Blood Cells

STEP	ACTION
1	Allow panel cells to come to room temp
2	Gently resuspend Reagent Red Cells, avoid creating bubbles or foam
3	Label bottles with an open date and Tech ID
4	Remove red caps and place them on the reagent rack cap holder below their corresponding bottle. **NOTE:** Alternatively, caps may be labeled to avoid contamination
5	Load panel reagents onto 3ml reagent rack labeled R3B with barcode labels facing out
6	Touch <Resources>
7	Touch <Reagents>
8	Touch the rack position to be loaded Note: Panel cells can be loaded onto positions 1,2,3
9	Touch <Load/Unload>
10	Open the door once unlocked and load reagents onto the selected postion **NOTE:** The instrument will run an inventory of reagents and post them in green when ready to use
11	**If reagents are** / **Then** Posted in green / Go to next step Not read by analyzer / Go to next secton **Manual Assignment of Reagents**
11	Close load station door

Manual Assignment of Reagents

Step	ACTION
1	Touch <Resources>
2	Touch <Reagents>
3	Touch the reagent displayed in red with the comment “barcode unreadable”
4	Touch <Assign to position>
5	Open the load station door when unlocked
6	Touch the rack position to be loaded **NOTE:** Reagent red cells can go in positions 1, 2, 3
7	Select the following parameters **Parameters** / **Touch** Reagent kit / Appropriate reagent Lot / Lot corresponding to reagent Confirm reagent / Reagent being loaded
8	Close the Load Station Door

Loading Diluents

STEP	ACTION
1	Label diluents with open date and tech ID **NOTE**: ID-MTS™ Diluent 2 and ID-MTS™ Diluent 2 Plus can be kept on board for up to 24 hours
2	Label reagent caps with corresponding diluent name ie. 2 or 2+ **NOTE:** There is no diluent cap holder on diluent reagent rack.
3	Load diluent bottle on the diluent rack with barcodes facing out
4	Touch < Resources>
5	Touch <Reagents>
6	Touch <Position 4>
7	Touch <Position 4>
8	Touch <Load/Unload>

STEP	ACTION
9	Open the load station door when unlocked and load diluent rack into position 4
10	Close the load station door **NOTE:** Analyzer will inventory diluents and post them in green when ready to use

Loading Dilution trays

STEP	ACTION
1	Touch <Resources>
2	Touch <Dilution Trays> **NOTE:** All dilution trays and wells display from position 1 to position 6.
3	Touch the position the dilution tray is to be loaded
4	Touch <Load/Unload>
5	Open the load station door when unlocked
6	Load the dilution tray onto the upper loading dock of the outer rotor and load the dilution tray onto the upper loading dock of the outer rotor
7	Close the load station door **NOTE:** Analyzer will automatically inventory trays

Unloading Reagents, Diluents and Dilution Trays

STEP	ACTION	
1	Touch < Resources	
2	Touch <Reagents>	
3	**If unloading**	**Touch**
	Reagent red Cells	• Rack to be unloaded
	Diluents	• <Position 4>
	Dilution trays	• < Dilution Trays> • Touch the rack to be removed – completely used racks display in red
4	Touch<Load/Unload>	
5	Open the door when unlocked and remove the resource **NOTE:** Additional resources may be loaded at this time	

STEP	ACTION
6	Close load station door

Loading MTS Cards

STEP	ACTION
1	Touch <Resources>
2	Touch <Cards>
3	Touch <Load/Unload
4	Open the Card Supply Drawer when unlocked and load card sleeve into any open position I**MPORTANT**: If loading a sleeve with more than one lot, leave an empty slot between lots
5	Close the Card Supply Drawer **NOTE:** Analyzer will automatically inventory card and post cards available for use

Filling Liquids and Discarding Liquid Waste

STEP	ACTION
1	Touch <Reasources>
2	Touch <Liquids> **NOTE**: A diagram showing DI water and Saline will display
3	Touch <Refill>
4	Open the Liquids Access Door when unlocked **NOTE:** The system will prompt you to refill the containers and empty the liquid waste
5	Pull the release for the liquids container
6	Remove the container from the system
7	Remove the white bottle cap
8	Fill the white container with approximately 4700ml of Saline
9	Reinstall the cap
10	Remove the blue bottle cap

STEP	ACTION
11	Fill the blue container with approximately 900 mL of DI water
12	Reinstall the cap
13	Slide the liquids container into the system manually or using the bottle insertion tool until it snaps into place
14	Pull the release for the grey liquid waste container
15	Remove the waste container from the system
16	Remove the black bottle cap
17	Dispose of the liquid waste in a dirty sink
18	Reinstall the cap
19	Slide the waste container into the system manually or using the bottle insertion tool until it snaps into place
20	Close the Liquid Access Door
21	Touch <Yes> whe the system prompts " Have you filled the Saline/Deionized Water Containers completely and emptied the Liquid Waste Container?" **NOTE:** The Executing Flush bar appear. After the flush is complete the screen will return to the original liquids screen showing the new levels of liquids detected

Emptying Card Waste

STEP	ACTION
1	Touch <Resources>
2	Touch <Waste> **NOTE:** A diagram showing how full both the card waste and the liquid waste is will display
3	Touch <Empty Cards>
4	Open the Card Waste Drawer when unlocked
5	Remove white waste tray
6	Dispose of the cards in a biohazard container
7	Reload the Waste Tray
8	Close card waste drawer

STEP	ACTION
9	Touch <Yes> when the system prompts " Has the card waste been emptied and the Waste Tray been put back into the instrument?"

Accessing Manual Load/Review

OVERVIEW

Cards requiring review are moved to the Dual Purpose Drawer. This drawer is made up of two sections.

Section	Number of Slots	Purpose
Front (removable rack)	10	The system moves cards to this rack when: • Visual review is require • There is no room in the room temperature incubator • Partially used cards are not used within 4 hours. **NOTE:** If partially used cards is not used within 4 hours or there is no available space in the room temperature incubator; the card is discarded in the waste drawer
Back (fixed rack)	8	User loads partially used and specialty cards in the section. The system will utilized these cards for testing.

Step	ACTION
1	Touch <Resourses>
2	Touch <Manual Load/Review>
3	**If card(s)** / **Then** Are present / Touch each card on the system screen to see the output reason Not present / Go to next step
4	Touch <Load/Unload>
5	Open the dual purpose drawer when unlocked
6	Remove and visually inspect any cards in the drawer. **If card(s) are** / **Then** From the incubator / Visually inspect them and reload in one of the 8 input slots From testing / Take them out and review in the results area- refer to SOP *Ortho Vision Results Management* **NOTE:** Partially used cards may be reloaded in one of the 8 slots on the rear rack for use after review is complete.

Resolving Error Messages

STEP	ACTION
1	Touch <Errors> **NOTE:** The Errors screen displays and allows review of the status of Errors that have occurred on the system.
2	Select an error by touch the screen
3	Touch <Show Details> action button **NOTE:** The Errors details screen is displayed for the selected error
4	Take the necessary steps to resolve the error
5	Document resolution under comments • Touch <Edit Comment> action button. • Enter Comment • Touch <Save>
6	Touch <Resolve> action button **NOTE:** The error state changes to resolved
10	**If the <Clear Error> button** / **Then** Is available / Touch the <Clear Error> action button to remove the error from the list and remove error status indicators for the error Not available / • The error is not resolved • Error that are not resolved and require OrthoTechnical Support, document on *Ortho Vision® Troubleshooting Log*

CALIBRATION:
NA

PROCEDURE NOTES AND LIMITATIONS:

- The System will automatically log out the user after 60 minutes.
- Emergency shutdown should only be performed if normal shutdown procedures are not available. All test processes are stopped immediately, tests will be failed and any results are lost. Pending tests will not begin. Emergency shutdown can be performed at any time and does not require user login.
- The reagent screen allows the user to load and unload reagents and review and manage reagent lots

REFERENCES:

OrthoVision® Analyzer General Operator Training Manual
OrthoVision® Analyzer Quick Reference Guide
Ortho Clinical Diagnostics Ortho Vision Analyzer Self Service Customer Procedure Guide
OrthoVision® Reference Guide

RELATED DOCUMENTS
FORM OrthoVision® Troubleshooting Log
SOP OrthoVision® Results Management
SOPOrthoVision® Resource Management and Daily Quality Control

APPENDIX:
Appendix 1:System Performance Characteristics and Specifications

<table>
<tr><th>Characteristic</th><th>Description</th></tr>
<tr><td>Technology</td><td>Column Agglutination with use of MTS Gel Cards</td></tr>
<tr><td>Test Menu</td><td>• ABO/Rh Typing
• Antibody Screen
• Antibody Identification
• Direct Antiglobulin Testing
• Antigen Testing
• QC Testing
• Serial Dilution for Titration Studies</td></tr>
<tr><td>Sample Type</td><td>• Centrifuged whole blood
• Plasma and Serum
• Packed red blood cells</td></tr>
<tr><td>Sample Tube Sizes</td><td>• 12-13 x 100mm
• 12-13 x 75mm
• 10 x 75mm</td></tr>
<tr><td>Sample and Test Processing</td><td>• Continuous,
• Random
• STAT access
• Batch</td></tr>
<tr><td>Plumbing</td><td>Self contained, on board liquid waste management</td></tr>
<tr><td>Centrifuge</td><td>Speed: 1004-1024 rpm</td></tr>
<tr><td>Incubator</td><td>• Cards incubated at 35-39^{0}C for at least 15minutes
• Room temperature incubator maintained at 21-27^{0}C</td></tr>
<tr><td>Pipette Performance</td><td><table><tr><th>Volume</th><th>Accuracy and Precision</th></tr><tr><td>10µl</td><td>10%</td></tr><tr><td>25µl</td><td>5%</td></tr><tr><td>50µl</td><td>5%</td></tr></table></td></tr>
<tr><td>Pipette Volume Verification</td><td><table><tr><th>Volume</th><th>Acceptance</th></tr><tr><td>10µl</td><td>≤10%</td></tr><tr><td>50µl</td><td>≤5%</td></tr></table></td></tr>
<tr><td>Wash Pump</td><td>Dispenses liquids at ≥2ml per second</td></tr>
</table>

Characteristic	Description
Load Station Temperature	Agitated inner rotor is maintained at 18-25^{0}C
Load Station Capacity	Non Agitated area • 6 Sample racks • 6 Dilution trays • 1 dliuent rack Agitated area • 3 RBC reagent rack (3ml and 10ml rack
Diluent Supply	• 2 100ml positions-MLS Diluent 2 and 2 Plus • 2 10ml positions-Titer diluent
Supply Drawer Capacity	120 Cards
Sample Capacity	42 samples (7 samples per rack)
Waste Capacity	• Waste Tray- 80cards • Liquid waste bottle holds 5.2L
Centrifuge Capacity	10 cards
Incubator Capacity	• Heated- 12 cards • Room Temperature- 16 cards

Appendix 2: System Overview

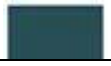
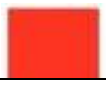
Home Dashboard	
	
System Home Dashboard	Displays the status of • Reagents • Samples • Results • STAT Orders
Menu Buttons	Are located horizontally along the top of the user interface and are used to display different menu screens. The buttons are divided into high traffic and low traffic menus
High Traffic Menus	Include the areas of the software used to process tests: 1. Home 2. Resources 3. Samples 4. Results 5. Errors 
Low Traffic	Use the expand button to display the low traffic menu buttons. 6. QC 7. Setup 8. Software 9. Maintenance 10. Diagnositcs 

Screen Layout		
		
1	Menus	Displays different menu screens.
2	System Name and Log Display	Displays the System Name, the J Serial Number, the installed software version, and the Instrument State. **Note**: The System Name and Logo Display are hidden when all tabs are expanded.
3	Indicator	Displays the current date and time and the user name currently logged into the system.
4	Tools	Tool buttons are located vertically along the right-side of some menu screens. Use Tools to navigate through screens within the selected menu. A selected item displays a white background.
5	Menu Screen	Displays the content of the selected Menu and Tools. Use the Menu buttons to toggle between screens.
6	Action Buttons	Executes actions within the current menu screen. Buttons change according to the menu displayed.
7	Assistance Buttons	The Search, Help, and Stop Processing buttons are displayed on all screens.
8	Expand Button	Touch the Expand button to display all of the menus. To collapse, touch the Expand button again.

Appendix 3: Status Indicators for Racks, Samples, Reagents and the Supply Drawer

State	Color and Icon	Description
Not Present		There is no Sample Rack, Card Sleeve or Reagent Rack at the current position.
Not Present		There is no sample, Card Sleeve, or reagent at the current position.
Present		The system location and/or position is ready for use.
Allocated		A sample or resource at the location is related to an order that is processing.
Scanning		The position or system location is currently being scanned by the system.
Removable		All pipetting has completed for the sample or all samples loaded in the SAMPLE RACK and the item is ready to be removed from the system.
Warning		Indicates that there is a warning.
Error		Indicates that there is an error with a severity level of Problem or Critical.

Appendix 4: Status Indicators for Dilution Tray Wells

State	Color	Description
Not Present		The dilution well has been used.
Present		The dilution well has not been used.
Allocated		The dilution well is allocated for processing.
Scanning		The dilution well is currently being scanned by the system.
Warning		Indicates that the dilution well has a warning.
Error		Indicates that there is an error with a severity level of Problem or Critical.

UWMC SOP Approval:			
UWMC CLIA Medical Director	Mark H. Wener, MD	Date	
Transfusion Service Manager	Nina Sen	Date	
Compliance Analyst	Christine Clark	Date	
Transfusion Service Medical Director	Monica Pagano, MD	Date	
UWMC Biennial Review:			
		Date	
		Date	