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1.0 Purpose

This document identifies the resources to be used on the Vision analyzer as well as their proper storage and handling requirements. Instructions include how resources are to be placed on the analyzer and monitored for replenishment, removal and lot tracking.

2.0 Scope


CLS trained and deemed competent to perform routine testing on the Vision Analyzer.

3.0 Definition of Terms

3.1 Resources refers to MTS red cell reagents, MTS Gel cards, diluents, deionized water, saline, and disposable items such as evaporation caps, and dilution trays.

4.0 Materials


Materials	Storage requirements	Use requirements	Comments
MTS [®] A/B/D Monoclonal and Reverse Grouping Card	2-25°C	Room temperature	Store in an upright position
MTS [®] Anti-IgG Card MTS Anti-IgG-C3d	2-25°C	Room temperature	Store in an upright position
MTS [®] Diluent 2 Plus	2-8°C	Room temperature	Used for ABD & Reverse testing. Diluents must not be left on the instrument longer than 24 hours.
MTS [®] Diluent 2	2-8°C	Room temperature	Diluents must not be left on the instrument longer than 24 hours.
0.8% AFFIRMAGEN [®] Reagent Red Blood Cells	2-8°C	Room temperature	Acceptable for onboard use of up to 5 continuous Days of on-board storage with the use of Evaporation Caps.
0.8% SURGISCREEN [®] Reagent Red Blood Cells	2-8°C	Room temperature	Acceptable for onboard use of up to 5 continuous Days of on-board storage with the use of Evaporation Caps.
Ortho RESOLVE [®] Panel A/B/C Reagent Red Cells	2-8°C	Room temperature	Reagent Red Blood Cells Resolve panels must be removed and stored 2-8°C when not in use.













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Evaporation Caps Dilution Trays Deionized Water Saline			
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5.0 Procedure

Steps	Action
1.	<p>Resources Menu</p> <p>Touch the Resources button to access the Resources screen. Use the Resources screen to monitor, discard, and replenish resources as needed. Select a button along the side of the Resources screen to display information about each resource.</p>
2.	<p>Resources Overview</p> <p>The Resources Overview screen allows the user to view a picture of the system in the Diagram View or a list in the Table View. In the Diagram View, notice an icon on each accessible area of the system. The buttons along the side of the screen display the same information about the system. Touch an icon or a button along the side of the screen to access an area of the system. The Diagram View is seen here:</p> <div data-bbox="462 1003 1047 1507" data-label="Image"> </div>
3.	<p>Resource Action Buttons</p> <p>Resource Action buttons are located in a horizontal bar at the bottom of each screen. Use these buttons to prompt an action on the data or contents of the current screen.</p>


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Action Button	Name	Description
	Assign to Position	Displays the Assign to Position wizard.
	Change View	Switches the display between a diagram view and a table view.
	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 the user through the process of emptying the Cards container.
	Load/Unload	Starts a wizard which guides the user through the process of loading/unloading reagents.
	Pause Auto Refresh	Pauses the automatic update of table information and changes the text of the button to Start Auto Refresh. Touch the Start Auto Refresh button to resume the automatic update.
	Refill	Starts a wizard which guides the user through the process of refilling the Deionized Water and Saline.
	Register OCD Lot	Starts a wizard which guides the user through the process of adding an OCD Lot.
	Register User Defined	Starts a wizard which guides the user through the process of adding a User Defined Lot.
	Show Inventory Report	Displays information about the quantity of consumables on-board the system.
	Show Lot Switch Log	Displays information about the product name, Lot ID, and first use.


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	Show Usage Statistics	Displays information about used/unused consumables. Number of orders failed/finished. Number of tests started/reportable/finished/failed. Number of test results started/ indeterminate/ finished or failed.
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Steps	Action
4.	<p>Reagents The Reagents screen allows the user to review current inventory information for the Reagents loaded on the system.</p> <ol style="list-style-type: none"> 1. Touch Resources > Reagents to access this screen. <ul style="list-style-type: none"> • Use this function to evaluate inventory and manage Reagent Lots. 2. The user can also load and unload Reagents as necessary. Touch the Load/Unload button. 3. Touch Show Details while in the Table View of the Resources screen. <ul style="list-style-type: none"> • Information is displayed in the Diagram View. The appearance and data displayed varies based on the barcode. 4. CLS are responsible for tracking all resources placed on the analyzer including numbers, quantity and all expiration outdates.
5.	<p>Reagent Handling</p> <ol style="list-style-type: none"> 1. Reagent red cells must be gently inverted to mix. Mixing is considered complete when the reagent red cells are completely suspended in the diluent. 2. Place reagent red cells in an appropriate REAGENT RACK. 3. If any bubbles are on the top of the meniscus, they must dissipate before loading on the analyzer. 4. Avoid agitation which could cause bubbles in the fluids. 5. Remove any bubbles from the surface of the fluids prior to processing. 6. Take care to maintain appropriate concentration and integrity of the liquid reagents. 7. Reagent red blood cells and diluents must be at room temperature when they are loaded on the analyzer. 8. Make sure to load agitated and non-agitated reagents in their proper locations – <ul style="list-style-type: none"> • Agitated (INNER ROTOR) – temperature is maintained at 18 – 25 °C. • Non-Agitated (OUTER ROTOR) - temperature is monitored at 18 – 25 °C.. • Refer to the Instructions for Use for information about a specific reagent. <p>If there is suspicion of testing performed with reagent red cells that were contaminated or not completely suspended,</p> <ol style="list-style-type: none"> 1. Discard the entire set of the reagent red cells. 2. Repeat testing with a new set of reagent red cells.

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	<p>Do not store reagent red blood cells that require agitation onboard the analyzer if the analyzer is going to be powered off or in maintenance mode.</p> <ul style="list-style-type: none"> • If reagent red blood cells that require agitation are left on-board the system after the system has been powered off or has been in maintenance mode, the reagent red blood cells will be marked unusable. <p>Opened Ortho Reagent Red Blood Cells can be affected by evaporation,</p> <ul style="list-style-type: none"> • Particularly in laboratory conditions of low humidity and high temperature. • In extreme laboratory conditions, such as 15% relative humidity and a temperature of 30° C, excessive evaporation of Ortho Reagent Red Blood Cells reagent may be observed and result in analyzer error. <p>Evaporation caps are disposable caps the user places on the Reagent Red Blood Cell vial.</p> <ul style="list-style-type: none"> • Evaporation caps fit 10 mL vials. • The cap is intended to allow access to the metering 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. <p>A1 and B Cell and 0.8% Surgiscreen</p> <ul style="list-style-type: none"> • The 10 ml Vials have been validated for continuous. • Continuous use onboard the analyzer up to 5 days when using the ORTHO VISION[®] Evaporation Cap. • Manual tracking of the 5 day outdate is done using the Vision Maintenance and QC Log. <p>0.8% Panel reagent red cells</p> <ul style="list-style-type: none"> • Must be capped and returned to 2 to 8°C when not in use. <p>MTS[®] Diluent 2 and MTS[®] Diluent 2 PLUS</p> <ul style="list-style-type: none"> • Two sets of Diluent 2 and Diluent 2 Plus. • One set is onboard the analyzer and one set is refrigerated. • The sets are switched out every 24 hours.
<p>6.</p>	<p>Reagent Lots Module</p> <ol style="list-style-type: none"> 1. Touch Resources > Reagent Lots to access this screen. <ul style="list-style-type: none"> • Use this module to register lots that analyzer fails to read barcode. • Use this module to view information about reagent kits. 2. Information on this screen include: <ul style="list-style-type: none"> • Lot ID – The Lot ID of the reagent. • Expiration Date – The Lot’s expiration date. • Consumables loaded – Reagents loaded at this time. • QC – If this is a sample-based quality control, a list of the quality control passed profiles is displayed. • Reagent Kit – The name of the reagent kit or reagent family associated with the lot. • User defined – An indicator marks the associated reagent kit as user defined.

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7.	<p>Dilution Trays</p> <p>The Dilution Trays screen allows the user to view information about the availability and position of dilution wells.</p> <ol style="list-style-type: none"> 1. Touch Resources > Dilution Trays to access this screen. 2. Dilution TRAYS must be used only once. 3. Discard used TRAYS into the bio hazardous waste container.
8.	<p>Cards</p> <p>The Cards screen displays information about the Cards loaded onboard the analyzer and missing card for an ordered test. Use this screen to view the Card type as well as errors and warnings.</p> <ol style="list-style-type: none"> 1. Touch Resources > Cards to access this screen. 2. Touch a card in the sleeve image to see information about that specific card. 3. Touch Change View to see information in a table format about the cards e.g. card type, quantity available, quantity needed, lot#, lot expiration date, location. <p>Card Foil</p> <ol style="list-style-type: none"> 1. Make sure the foil is sealed properly over all columns. 2. Do not load cards with dried out unused gel columns. 3. Do not manually punch the foil. 4. The analyzer will automatically punch the foil over the correct columns before running the test. 5. Before loading cards onto the analyzer, make sure the cards do not contain any liquid on the foil. 6. Cards with liquid on the foil may cause contamination of the GRIPPER or PUNCH TOOL. 7. Discard cards with liquid on the foil.

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	<p>Load Different Unused Card Types in one Sleeve</p> <ol style="list-style-type: none"> To load a sleeve with different card types or lot#, leave an empty slot between the cards. The analyzer assumes resources in groups separated by an empty slot are the same card type or lot#. Do not mix cards within a group. <p>Supply Drawer The SUPPLY DRAWER is monitored at a temperature between 18°C-33°C.</p> <ol style="list-style-type: none"> If the analyzer detects resources are outside of the temperature range, results will either be flagged or not reported Do not use the Supply Drawer to store resources. Cards must be kept upright with the foil facing up at all times. <p>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.</p> <ol style="list-style-type: none"> Upon receiving an error free result, the card is placed in the RT Incubator. Partially used cards can remain in the RT Incubator, and be used for additional test processing, for up to 4 hours. If a partially used card is not used within 4 hours, the analyzer will move the card from the RT Incubator to the Manual Review Rack for quality check by user. User can load partially used cards on the analyzer by placing them in the LOAD AREA of the DUAL PURPOSE DRAWER. NOTE: There is a maximum of 6 slots in the RT Incubator allocated for partial cards. Do not load more than 6 partial cards. To see partial cards in the RT Incubator, touch Resources > Cards > Change View.
<p>9.</p>	<p>Waste The Waste screen displays the current status of the WASTE DRAWER, and the LIQUID WASTE BOTTLE.</p> <ol style="list-style-type: none"> Touch Resources > Waste to access this screen. The information displayed is: <ul style="list-style-type: none"> Total Capacity – Available fill leve Free Capacity – Estimated available fill leve Time Until Full – An expected fill level and estimated time until the fill level is reached.

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10.	<p>Liquids The Liquids screen allows the user to monitor the availability of deionized water and saline on the system.</p> <ol style="list-style-type: none"> 1. Touch Resources > Liquids to access this screen. 2. 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. 3. Only fill with liquids at RT. 4. Do not mix the liquids; avoid agitation which could cause bubbles in the liquids. 5. The liquid waste container must be emptied at the same time when the liquid containers are refilled.
11.	<p>Manual Load / Review The Manual Load/Review screen allows the user to view the status of loaded partial cards and any cards that require manual review.</p> <ol style="list-style-type: none"> 1. Touch the Resources > Manual Load/Review button to access this screen. <ul style="list-style-type: none"> • The Manual Load/Review screen provides access to the Manual Review function and access to the LOAD AREA in the DUAL PURPOSE DRAWER. 2. A result requires manual review when one or more of the following applies, at least one of the selected options for automatic result acceptance is not fulfilled: <ul style="list-style-type: none"> • The pattern of interpreted assays does not match with any of the predefined test results. • The result is flagged for review. • The reaction grades do not meet threshold criteria.

6.0 Documentation and Records


6.1	Document change of red cell reagents and diluents on the VISION Maintenance and QC Log .
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7.0 Related Documents

7.1	Ortho Vision Routine Testing SOP.
7.2	Vision Maintenance and QC Log.

8.0 References

8.1	ORTHO Vision [®] Analyzer ID-MTS [®] Gel Cards Reference Guide, current revision
8.2	ORTHO Vision [®] Analyzer ID-MTS [®] Gel Cards Self-Service Customer Procedures Guide, current revision.

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8.3	Ortho Clinical Diagnostics, Gel Card Fast Facts BB10407 Dec. 2008.
8.4	Ortho Clinical Diagnostics, IFU, current revisions.