|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **Ortho Vision Max Analyzer**  **Start up/Shut Down/**  **Maintenance Including QC** | **Dept:** | 324311 |
| **Dept Name** | Blood Bank |
| **Effective Date:** | Title21 |
| **Revised Date:** | Title21 |
| **Name & Title**: CLIA Laboratory Medical Director | | | **Contact:** | Julie H Simmons/  Christina S Warren |
| **Signature:** | Refer to Title 21 | | **Date:** | **Title 21** |

**1. General Procedure Statement:**

**A.** **Purpose:**

ORTHO VISION® Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS® gel card technology. 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. ORTHO VISION® Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

**B.** **Responsible Department/Scope:**

1. Procedure owner/Implementer: Julie H. Simmons/Christina S. Warren
2. Procedure prepared by: Julie H Simmons
3. Who performs procedure: Department staff/management

**C. Definitions:**

ID-MTS®: ID-Micro Typing System® or the ID-MTS® Gel Test is the technology that uses dextran acrylamide gel particles suspended in liquid reagents to trap agglutinates following antigen-antibody reactions.

QC: Quality control is the necessary testing and/or functional checks to ensure that personnel, reagents, and equipment are producing reliable and accurate results.

SOPs: Standard Operating Procedures contain the details or instructions of specific steps in a process that must be followed by operators.

**D. Sections**:

I. Start up and Shut down

II. Maintenance

A. Daily

B. Weekly

C. Monthly

III. Quality Control

1. Running a QC Sample
2. Changing QC Lots
3. QC of Different ID-MTS Gel Card Lots or Reagent Red Cell Lots
4. Printing QC Results/Show QC History
5. Managing Failed QC Results
6. Pipette Carryover

**E. Protocol**

Introduction

1. Touch Maintenance to display the Maintenance screen.
2. The Maintenance screen allows you to view and maintain a schedule of Maintenance Tasks that must be performed to keep the system operating at an optimal level.
3. Use the Maintenance screen to monitor and execute required Maintenance Tasks.
4. Select an action button along the bottom of the Maintenance screen to execute procedures with Maintenance Wizards or create a Maintenance Report.
5. All maintenance tasks must be completed successfully. If maintenance is not completed on time, then the results are flagged and an error message is displayed on the screen.
6. Assume that all used equipment is contaminated with potentially infectious biological material

Note: In the United States, use the “Universal Precautions” recommended by OSHA (Occupational Safety and Health Administration) Bloodborne Pathogen Standard 29CFR1910.1030 when handling, cleaning, and packing equipment.

In particular:

* Wear gloves, closed shoes, buttoned lab coats, and safety glasses when the system is cleaned and maintained.
* Treat all waste materials used in the cleaning process as contaminated. Follow the site procedures for your laboratory to dispose of these materials.
* Handle all equipment with care. Mechanical parts may have edges, pinch points, and corners that potentially could cause injury.
* Liquid may drip from disconnected tubing. If necessary, use an absorbent material to absorb the drops of liquid.

**2. Procedure:**

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: NA

Reagents: NA

Equipment: Ortho Vision Max

Specimen Requirements: NA

Notes:

Qualified Ortho Clinical Diagnostics service personnel will perform initial system startup and setup. After initial startup and setup, you do not need to shut the system down; the system is intended to remain in operation 24 hours a day. When not in use, the system continues to control the environmental conditions of stored liquids and reagents. Environmental conditions are not controlled when the system is shutdown. The system should be restarted if you experience excessive rates of slow system responses.

IMPORTANT: The system should be restarted if you experience excessive rates of slow system responses.

**Section I: Start up and Shutdown**

*Refer to Power Up & Shut Down Job Aide*

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **Start up**  **Start up** | **System Setup**  If the system is off, you must start it and load system fluids and supplies.   1. Confirm the Load Station is empty. Samples and agitated reagents should not be in the Load Station at startup.  * If any samples are found on board, they will be marked as expired. * If any liquid reagents are found in the agitated supply, they will be marked as requiring agitation.  1. Confirm the Card Waste Tray is emptied. 2. Close all the doors. 3. Confirm the system is connected to a power outlet. System should actually be plugged into the UPS, which should be plugged into a proper power supply and turned on. 4. Press the ON switch located on the lower right side of the system.   On startup, there is short time period for logon with maintenance permissions (**Diagnostic** button on the screen available to Field Service or Key Operator as directed by Service). Note that the system does not initialize after the Service Log in, leaving the system in a maintenance state. If the operator does not touch the Diagnostics button, the software continues the startup process. Normal startup A normal system startup leaves the system in Operational state. The system will perform device and consumables inventories. The system will post an error for the Incubator (37° C) ring until the temperature is reached. Startup after an urgent shutdown If starting up after an urgent shutdown, any orders in the work list/database with status Running will be flagged as aborted. The system will discard any cards found onboard and perform an inventory. Startup and Shutdown Procedures:Power-on The Power-on switch is located on the right side of the analyzer. Turn it on and wait for the system to initialize. Make sure power cable is plugged in. System should actually be plugged into the UPS, which should be plugged into a proper power supply and turned on. Once powered on, the system completes a series of initialization processes, which include:   * Hardware Initialization * Component Inventory * Consumable Inventory   IMPORTANT: 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. |  |
| **Shut down**  **Emergency Shut down** | Shut Down the System Use this procedure to perform an orderly shutdown of the system. This procedure is accessed from the Home screen.   1. Remove samples, reagents, etc. 2. **Touch** the Home menu button. 3. **Touch** the Shut Down action button. 4. A confirmation screen is displayed. 5. **Touch** Yes to confirm the shutdown procedure. Shutdown processing begins. Before turning off the power, confirm that the green light under the monitor is blinking and that the “No signal Detected” message has displayed. 6. **Power off** the Ortho Vision®Analyzer with the power switch, located on the right side of the analyzer. 7. The system shuts down.  Emergency Shutdown IMPORTANT: An emergency shutdown should only be performed if normal shutdown procedures are not available.  To perform an emergency shutdown, touch the Stop Processing button from any screen and choose the Perform Urgent Stop option. The system must then be restarted.  IMPORTANT: 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.  Note: An emergency shutdown can be performed at any time. A user does not need to be logged in; therefore, the user who performed the emergency shutdown may not be recorded. |  |

**Section II: Maintenance**

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Clean, lint-free cloth, Paper towel, Cotton swabs, Soft, nylon-bristle brush

Reagents: Distilled or deionized water, 70% isopropyl alcohol, NaOH, Warm, soapy water

Equipment: Ortho Vision Max

Specimen Requirements: NA

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Maintenance Mode** is an Instrument State that is safe for Maintenance Tasks to be executed.   * 1. The system must be in Maintenance Mode in order for Maintenance Tasks to be performed.   2. The Instrument State, displayed in the top-center of the screen indicates when the system is in Maintenance Mode.   3. When in Maintenance Mode, the Maintenance screen is available. The Maintenance Tasks and Action Buttons on the screen are active. System doors are monitored so that the appropriate inventory and initialization processes can be performed once Maintenance Tasks have been completed.   4. To exit Maintenance Mode and return the system to the Operational state, touch   another Menu.  Note: If the system is not in Maintenance Mode, only the status of Maintenance Tasks can be viewed on the Maintenance screen. The system must be in Maintenance Mode to enable the Execute action |  |
| **2.0** | **Follow the steps below. Refer to diagram.**   * 1. Touch the Stop Processing button.   The system will ask if you want Urgent Stop or Stop Processing. Touch Stop Processing.   * 1. Touch the Maintenance menu button.   2. Touch Enter Maintenance Mode.   3. Select the desired maintenance frequency.   4. Select the desired maintenance task.   5. Touch the Execute action button.    Maintenance Wizards Maintenance Wizards are guided procedures that provide step by step instructions to assist you in the completion of Maintenance Tasks. To display a Maintenance Wizard, select a Maintenance Task and touch Execute.  **Note:** Touch the Help button to display Maintenance screen help and access system documentation. The Search and Stop Processing buttons are inactive when a Maintenance Wizard is in use.  The Maintenance Wizard displays steps and images for each Maintenance Task. For a Maintenance Task to be successfully executed, each step must be completed. If the Maintenance Wizard is closed before all the steps are completed, you must start the task over again.  Use the Action Buttons located in the black bar, below the images, to advance through the steps. |  |

1. **Daily Maintenance: Daily Probe Decontamination**

Users with the required access rights should perform each Daily Maintenance Task listed on the Maintenance-Daily screen. Daily Maintenance Tasks should require no more than 15 minutes, in total, to complete.

Be sure that the system is in Maintenance Mode before any Maintenance Task is executed. The Maintenance Task, listed below, is the default Daily Maintenance Task for the system:

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **When prompted, open the LOAD STATION DOOR.** |  |
| **2.0** | **Add 5 mL of 0.1 NaOH to a 10 mL vial with a supported barcode.**  2.1 Place the vial into position 3 of a DILUENT RACK. |  |
| **3.0** | **Place a new 5 mL vial of 7% BSA (REF: 6844285) into position 2. Load the DILUENT RACK.**  3.1 IMPORTANT: Use a new vial of BSA each time. Do not combine open vials. |  |
| **4.0** | **Close the LOAD STATION DOOR.** |  |
| **5.0** | **When prompted, open the MAINTENANCE DOOR.** |  |
| **6.0** | **Clean the PROBES with a lint free cloth moistened with 70% isopropyl alcohol.**  6.1 Be careful not to bend the PROBES. |  |
| **7.0** | **Close the MAINTENANCE DOOR.**  **Result: The system will automatically complete the decontamination.** |  |
| **8.0** | **When prompted, open the LOAD STATION DOOR.** |  |
| **9.0** | **Remove the DILUENT RACK.** |  |
| **10.0** | **Close the LOAD STATION DOOR.**  **Result: The system will indicate when the procedure is complete.** |  |

1. **Weekly Maintenance: Liquid System Decontamination and Pump Test**

*Refer to Weekly Maintenance Job Aide/Empty Waste & Replenish Liquids*

IMPORTANT: This procedure is accessed using system maintenance. Complete each task as prompted using the system software.

While the system is in normal operation, the LOAD STATION DOOR and MAINTENANCE DOOR are interlocked to prevent exposure to any dangerous movements. However, when loading and unloading supplies and performing maintenance or troubleshooting there are several areas in the system where the operator may be exposed to components that move

suddenly.

Use caution when working on and around the following system components:

• CENTRIFUGE

• GRIPPER ARM

• INCUBATOR

• LOAD STATION

• PIPETTE ARM

• DUAL PURPOSE DRAWER

Always exercise appropriate caution when operating the system and correcting any conditions..

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Open the Liquids Door and pull BOTTLE RELEASE for the LIQUID WASTE BOTTLE.** |  |
| **2.0** | **Remove the LIQUID WASTE BOTTLE from the system.** |  |
| **3.0** | **Remove the BOTTLE CAP.** |  |
| **4.0** | **Dispose of the liquid waste according to local regulations and your laboratory guidelines.** |  |
| **5.0** | **Install the BOTTLE CAP and slide the LIQUID WASTE BOTTLE into the system either manually or with the Bottle Insertion Tool, until it snaps into place.** |  |
| **6.0** | **Pull the BOTTLE RELEASE for the LIQUID CONTAINER.** |  |
| **7.0** | **Remove the LIQUID CONTAINER from the system.** |  |
| **8.0** | **Remove the 2 BOTTLE CAPS one after the other.** |  |
| **9.0** | **Dispose of the residual liquids.** |  |
| **10.0** | **Fill the smaller BOTTLE (blue) with approximately 400 ml of 70% isopropyl alcohol and the larger BOTTLE (white) with approximately 900 ml of 70% isopropyl alcohol.** |  |
| **11.0** | **Install the BOTTLE CAPS and gently tilt side to side.** |  |
| **12.0** | **Push the BOTTLE back into the system either manually or with the Bottle Insertion Tool, until it snaps into place.**  12.1 Close the DOOR.  **Result: The system will perform the decontamination.** |  |
| **13.0** | **When prompted, open the Liquids Door and pull the BOTTLE RELEASE for the LIQUID CONTAINER.** |  |
| **14.0** | **Remove the LIQUID CONTAINER from the system.** |  |
| **15.0** | **Remove the 2 BOTTLE CAPS.** |  |
| **16.0** | **Dispose of the liquids according to local regulations and your laboratory guidelines.** |  |
| **17.0** | **Fill the smaller BOTTLE (blue) with approximately 500 ml of deionized water and the larger BOTTLE (white) with approximately 3000 ml of deionized water.** |  |
| **18.0** | **Install the BOTTLE CAPS and gently tilt side to side to rinse.** |  |
| **19.0** | **Remove the 2 BOTTLE CAPS and dispose of the liquids according to local regulations and your laboratory guidelines.** |  |

1. **Monthly Maintenance: Instrument Cleaning**

*Refer to Monthly Maintenance Job Aide*

Monthly Maintenance Tasks should require no more than 60 minutes, in total, to complete.

Be sure that the system is in Maintenance Mode before any Maintenance Tasks are executed. The Maintenance Task, listed below, is the default Monthly Maintenance Task for the system:

IMPORTANT: This procedure is accessed using system maintenance. Complete each task as prompted using the system software.

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** | |
| --- | --- | --- | --- |
| **1.0** | **Open the Load Station Door.** |  | |
| **2.0** | **Remove all Racks and Trays from the Agitated (inner) and Non-agitated (outer)**  **Rotors.** |  | |
| **3.0** | **Clean all positions of the Agitated (inner) and Non-agitated (outer) Rotors.** |  | |
| **4.0** | **Open the Maintenance Door.** |  | |
| **5.0** | **Remove both Centrifuge Covers.** |  | |
| **6.0** | **Clean all surfaces of both Centrifuges. Remove and Clean Centrifuge Cards Holder.** | |  |
| **7.0** | **Install both of the Centrifuge Covers.** | |  |
| **8.0** | **Clean all surfaces of the Incubator.** | |  |
| **9.0** | **Close the Maintenance Door.** | |  |
| **10.0** | **Open the Load Station Door.** | |  |
| **11.0** | **Load an empty NAA Reagent Rack (labeled N02B).**  **Result: The Load Station will move to the reagent rack load position.** |  | |
| **12.0** | **Load an empty 10 mL Reagent Rack (labeled R10b) and close the Load Station Door.**  **Result: “The test completed successfully” message will appear.** |  | |
| **13.0** | **Open the Load Station Door.** |  | |
| **14.0** | **Unload the empty Reagent Rack.** |  | |
| **15.0** | **The Load Station will move to the reagent rack load position.** |  | |
| **16.0** | **Unload the empty Reagent Rack and close the Load Station Door.** |  | |
| **17.0** | **The test is complete.** |  | |

**Section IV: Quality Control**

*Refer to Quality Control Job Aide*

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: NA

Equipment: Ortho Vision Max

Reagents Required:

| 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 | 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 should not be left on the instrument longer than 24 hours. |
| 0.8% AFFIRMAGEN® Reagent Red Blood Cells | 2-8°C | Room temperature | Reagent red cells should not be left on the instrument longer than 5 days. Ensure reagent red cells are properly re-suspended prior to use.  Return reagents to refrigerated storage when not in use. |
| 0.8% SELECTOGEN® Reagent Red Blood Cells  or  0.8% SURGISCREEN® Reagent Red Blood Cells | 2-8°C | Room temperature |
| ABD & Reverse Controls:  Prepared samples. | 2-8°C | Room temperature | Verify samples are labeled appropriately.  Verify Lot # and expiration date on the samples. |
| Antibody Screen Controls:  Positive and negative antibody screen | 2-8°C | Room temperature | Verify samples are labeled appropriately.  Verify Lot # and expiration date on the samples (as applicable). |

1. **Running a QC Sample**

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Prior to running QC, load Resources**  *Refer to Daily QC Quick Reference Guide* |  |
| **2.0** | **Touch the QC menu button.** |  |
| **3.0** | **Select the profile you wish to process, and touch the Run QC Job action button.** |  |
| **4.0** | **Touch Save and Start.** |  |
| **5.0** | **Repeat steps 2 and 3 for all profiles requiring QC.** |  |
| **6.0** | **Touch Samples> then select a ring position into which you want to load samples.** |  |
| **7.0** | **Touch Load/Unload and open the door.** |  |
| **8.0** | **Select any additional ring positions into which you want to load QC samples.** |  |
| **9.0** | **Place the rack or racks in the Load Station and close the door.**  **Result: The system inventories and posts the samples.** |  |

1. **Changing QC Lots**

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Touch the QC menu button.** |  |
| **2.0** | **Select the profile you wish to process, and touch the Run QC Job action button.** |  |
| **3.0** | **To configure the QC, Touch > Change OCD QC Sample ID.** |  |
| **4.0** | **Enter the Barcode using the Handheld Barcode Scanner. This will enter the QC Lot# twice.**  4.1 If manually typing in the lot number information, type the barcode twice. |  |
| **5.0** | **Repeat steps 1-4 for each MBC Profile.** |  |

1. **QC of Different ID-MTS Gel Card lots or Reagent Red Cell Lots**

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Load all resources including all lots requiring QC.** |  |
| **2.0** | **Touch QC>Touch MBC Profile.** |  |
| **3.0** | **Touch Run QC Job.** |  |
| **4.0** | **Select Reagent Lots, and touch a reagent lot for each required reagent kit.**  4.1 If there is more than one reagent lot loaded on the instrument, the default  selection is the lot that was most recently registered.  4.2 Touch twice to view all lot numbers that are loaded on the analyzer. |  |
| **5.0** | **To Select Card Lots touch a card lot for each required card type.**  5.1 If there is more than one required card lot loaded on the instrument, the default  selection is the lot that was most recently registered.  5.2 Touch the card type twice to view all lots that are loaded on the analyzer. |  |
| **6.0** | **Select Manual Rev. Required (Manual Review Required), and touch Yes or No.** |  |
| **7.0** | **Touch Save.**  7.1 The system processes the QC job you requested. |  |
| **8.0** | **Repeat steps 1-7 to QC other lots that are loaded.** |  |

1. **Printing QC Results/Show QC History**

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **Printing QC Results** | 1. **1.0 Touch > QC.** 2. **2.0 Touch MBC (Profile Name).** 3. **3.0 Touch Show MBC Report.** 4. **4.0 Touch Print or Save.** |  |
| **Show QC History** | 1. **Touch QC > Touch the MBC Profile to view.** 2. **2. Touch Show QC History.**   D:\QC\QC ABORh history  20150812-151215  USB_TECAN,VISIONMAX,70000609.jpg |  |

1. **Managing Failed QC Results**

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Currently QC shows as failed even with modification to the QC result (example:? modified to Neg).**   * 1. These results can be rejected or accepted and then archived.   2. Repeat MBC QC samples that have failed for that MBC Profile.   3. Investigate repeated QC failures and notify management. |  |

**F. Pipette Carryover**

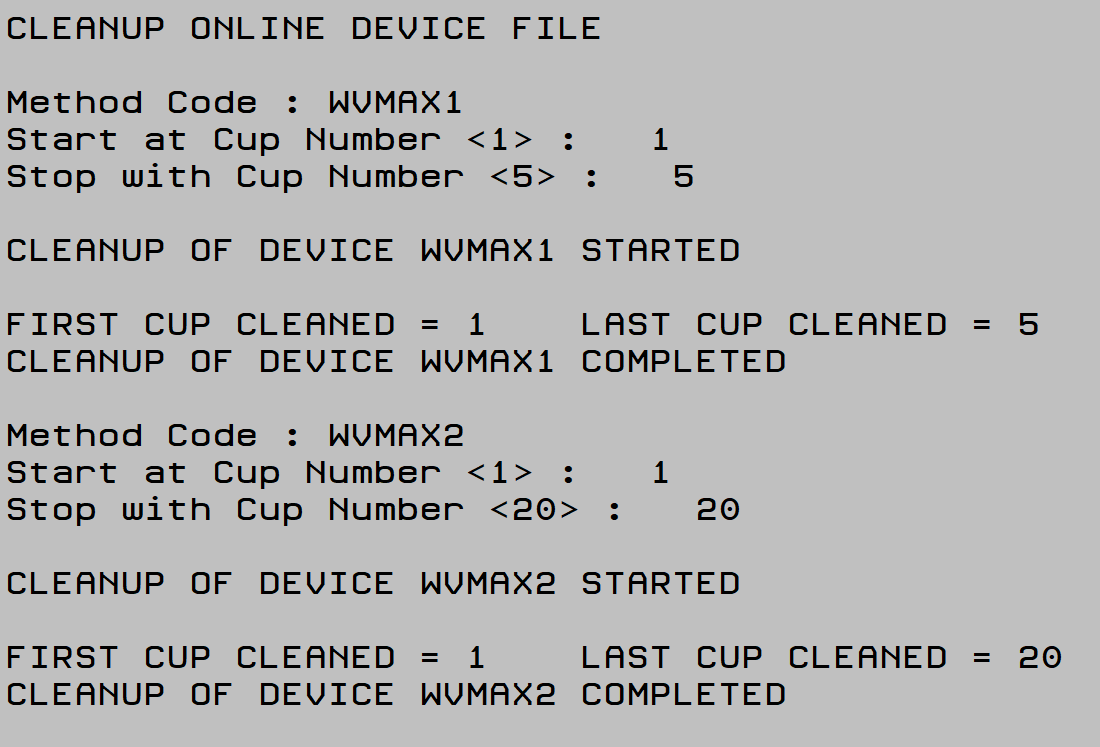
1. Pipette carryover will be investigated during further antibody workup.
2. Positive screens and unexpected results are not finalized until all reactivity is resolved.

**G. OFC Function in SmarTerm**

1. Daily after performing daily maintenance, the technologist will perform the OFC function in SmarTerm.

* Log in to Smarterm
* Function: OFC
* Method Code: WVMAX1 or VVMAX2
* Start at Cup Number <1>: 1 or Enter
* Stop with Cup number <#>: Enter

1. Example of report:



1. Only run a clean up on the vision that was QC’d.
2. Example: First shift will perform OFC of V1 daily while 2nd shift will perform OFC of V2 daily.

**3. Review/Revised/implemented:**

All procedures must be reviewed as stated in Document Control Protocol

All new procedures and procedures that have major revisions must be signed by CLIA Director.

All reviewed procedures and procedures with minor revisions can be signed by the

designated section medical director or designee.

**4. Related Procedures:**

**5. References**:

Ortho Vision Standard Operating Procedures

**6. Attachments**:

Power Up & Shut Down Job Aide

Quality Control Job Aide

Weekly Maintenance Job Aide

Monthly Maintenance Job Aide

Empty Waste & Replenish Liquids Job Aide

Daily QC Quick Reference Guide

**7. Revised/Reviewed Dates and Signatures:**

Refer to Title21