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-0072.02
TITLE: **Ortho Vision® Resource Management and Daily Quality Control**		

PURPOSE:

To provide instruction for performing reagent quality control (QC) on the Ortho Vision® and the use and handling of reagents, diluents, MTS gel cards and other materials.

PRINCIPLE & CLINICAL SIGNIFICANCE:

A quality control program is established to ensure reagents; antisera and the Ortho Vision® perform as expected prior to reporting of patient or blood component test results. Validity of routine test results are evaluated by testing the reagents with a commercially available QC kit and samples prepared according to manufacturer's recommendations. Quality control testing is considered acceptable if valid positive and negative results are obtained for each reagent tested.

Resources used with the analyzer must be tracked, monitored and discarded as per manufacturer requirements and expiration dates. The Resources screen is used to monitor, discard, and replenish resources as needed.

POLICIES:

- Quality control (QC) testing is performed:
  - Each day of use
  - Whenever a new reagent lot number is placed into use – this includes MTS Gel Cards
  - After maintenance (daily, weekly, monthly, yearly)
  - After service or repair of the analyzer
- QC testing is performed daily on both analyzers in use. Quality control results of a reagent on one analyzer, is not acceptable for use on the 2nd analyzer unless QC is repeated on the 2nd analyzer prior to reporting of patient or blood component test results.
- Unexpected results are investigated and resolved prior to reporting patient or blood component test results
- Each lot of reagent and MTS gel card in use is quality control tested and must meet acceptance criteria prior to verification and reporting of patient or blood component testing. Patient and blood component samples may be run in parallel with the control samples as long as this requirement is met.
- All antisera and cellular reagents are stored per manufacturer instructions when not in use
- Preparation of ABO/Rh and antibody screen controls may be necessary if AlbaQ-Chek samples are unavailable, expired or at an inadequate volume

- The supply drawer is not intended for reagent or diluent storage
    - 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

- **Table 1: MBC QC Test Profiles, Reagents, QC Samples** lists the QC Test Profiles required for daily QC and the MTS® Gel Cards, reagents, diluents and QC samples required for each. If circumstances prevent testing a QC Test Profile, patient and blood component samples will not be tested on the analyzer.
-
    - **DAILY:** The following Test Profiles are performed daily on each analyzer:
        - Type and Screen
        - Donor Rh Pos
        - Donor Rh Neg
        - DAT Poly
        - DAT IgG
    - **NO QC**: The following test profiles do not have a corresponding QC test profile. The reagents used are QC as part of the Type and Screen Profile which must be complete and acceptable prior to use of these test profiles:
        - Blood Type
        - Antibody screen
        - Cord Blood

Table 1: MBC QC Test Profiles, Reagents, QC Samples

QC Test Profile	MTS® Gel Card	Reagent Red Blood Cells	Diluents	QC Sample
Type and Screen	• MTS® A/B/D Monoclonal and Reverse Grouping Card • MTS® Anti-IgG Card	• 0.8% AFFIRMAGEN® Reagent Red Blood Cells • 0.8% SURGISCREEN® Reagent Red Blood Cells	MTS Diluent 2 Plus	• AlbaQ-Chek Level1- **QC1** • AlbaQ-Chek Level2- **QC2** • AlbaQ-Chek Level3- **QC3**
Donor Rh Pos	• MTS® A/B Monoclonal Grouping Card	N/A	MTS Diluent 2 Plus	• AlbaQ-Chek Level1- **QC1** • AlbaQ-Chek Level3- **QC3**
Donor Rh Neg	• MTS® A/B/D Monoclonal Grouping Card	N/A	MTS Diluent 2 Plus	
DAT Poly	• MTS® Anti-IgG, - C3d Polyspecific Card	N/A	MTS Diluent 2	• AlbaQ-Chek Level4- **QC4** (IgG C_3 NEG) • IgG POS prepared cells • C3 POS prepared cells
DAT IgG	• MTS® Anti-IgG Card	N/A	MTS Diluent 2	• AlbaQ-Chek Level4- **QC4** (IgG C3 NEG) • IgG POS prepared cells

- Resources are stored and used according to manufacture requirements and current Good Manufacturing Practices.
    - Storage and onboard stability requirements are found in **Table 2: Resource Storage Requirements and Onboard Stability.**
    - General specifications for use are listed in **Table 3: Use and Handling of Resources**

Table 2: Resource Storage Requirements and Onboard Stability

Materials	Storage Requirements	Use Requirements	On-Board Stability	Comments
MTS® A/B/D Monoclonal and Reverse Grouping Card	2-25°C	Room temperature	Refer to manufacture expiration date on card	• Store in an upright position
MTS® A/B/D Monoclonal Grouping Card				
MTS® A/B Monoclonal Grouping Card				
MTS® Anti-IgG,-C3d Card				
MTS® Anti-IgG Card				
MTS® Diluent 2 Plus	2-8°C	Room temperature	24 hours	• Diluents should not be left on the analyzer longer than 24 hours. • Change diluent bottles prior to performing daily QC
MTS® Diluent 2				
0.8% AFFIRMAGEN® Reagent Red Blood Cells	2-8°C	Room temperature	5 days (120 hours)	• 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% SURGISCREEN® Reagent Red Blood Cells				
IgG Coated Cells	2-8°C	Room temperature		• Discard after use for quality

Materials	Storage Requirements	Use Requirements	On-Board Stability	Comments
C3 Coated Cells			• Manufactured at time of quality control testing • Expires 24 hours after manufacture	control testing – May be used for same day automated and manual quality control testing prior to discard
AlbaQ-Chek® QC Kit:	2-8°C	Room temperature	• Used only during quality control testing • Stored in the reagent refrigerator • Vials expire 7 days from opening	Kit contains the following: • Vial 1 (QC1) – Group A RhD Negative (rr) containing Anti-B, Anti-D • Vial 2 (QC2) – Group O RhD Positive (R_1R_1) containing Anti-A, Anti-B, Anti-c • Vial 3 (QC3) – Group B RhD Positive (R_1r) containing Anti-A • Vial 4 (QC4) – Group A_2B RhD Positive

Table 3: Use and Handling of Resources

Resource	Specification for Use
Red Blood Cell Reagents, QC Samples, and Diluents	• Do not use any reagents including quality control samples if evidence of contamination is present.
	• Do not use if extreme turbidity, precipitation, or hemolysis is present
	• All reagent red blood cells and diluents must be at room temperature when loaded on the system

	• Prior to loading on the Vision, reagent red blood cells must be gently inverted to mix the red blood cells until they are completely suspended in the diluent:
	  ○ Reagents should not be agitated in a manner that will not cause bubbles in the fluids
	  ○ Remove any bubbles from reagent using an applicator stick or a transfer pipette before loading on the system
	• Care should be used to maintain the concentration and integrity of all reagents

	• If there is suspicion of testing performed with reagent red blood cells that were not completely suspended: ○ Discard the entire set of reagent red cells (ie: A1 and B cells, all 3 screen cells) and • Repeat testing with a new set of reagent red cells.

Resource	Specification for Use

Red Blood Cell Reagents, QC Samples, and Diluents	• Replace reagent caps on 10mL reagent red blood cell vials with disposable ORTHO VISION® Evaporation Cap prior to loading on the system to prevent evaporation of liquid. 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.
	  ○ ORTHO VISION® Evaporation Cap are intended to be single use and only used on reagent red blood cell vials
	  ○ Do not remove ORTHO VISION® Evaporation Cap from one vial and place on another vial
	• Discard used ORTHO VISION® Evaporation Cap when the vial is discarded

	• Freshly opened 0.8% Affirmagen®, and 0.8% Surgicreen® is validated, by the manufacturer, for 5 days (120 hours) on-board stability when ORTHO VISION® Evaporation Cap are used
	• Do not store reagent red cells that require agitation on-board the system when the system is in Maintenance Mode or if the system is going to be powered off. ○ Reagent red cells requiring agitation will be marked unusable if left on-board when the system is in Maintenance Mode or powered off.
	• Ortho Reagent Red Blood Cells 0.8% Affirmagen®, 0.8% Surgicreen®, Resolve® Panels A, B, C Untreated, and C Ficin should be capped and stored at 2 to 8°C when not in use
	• Freshly opened MTS® Diluent and MTS® Diluent 2 PLUS may be kept on the analyzer for up to 24 hours of continuous use. ○ Performance of MTS® Diluent 2 PLUS after 24 hours of continuous use on the analyzer has not been validated.
Dilution Trays	• Dilutions trays may be used only once. Once all wells are used, the tray should be discarded in a red biohazard container.
MTS® Gel Cards	• Do not load cards that appear dried out.
	• Make sure the foil is sealed properly over all columns.
	• Do not manually punch the foil. The system will automatically punch the foil over the correct columns before running the test.
	• Before loading cards to the system, make sure the cards do not contain any liquid on the foil. ○ Discard cards with liquid on the foil. Cards with liquid on the foil may cause contamination with the gripper or punch tool.
	• When loading a sleeve with more than one lot of the same type of gel card, leave an empty slot between lots.
	• Only load the same type of card in a single sleeve. The system assumes resources in groups separated by an empty slot are all the same type of test.
	• Sleeves must be stored upright with the foil always facing up.
	• **Partially used cards** are placed in the room temperature incubator by the system and may remain there for up to 4 hours.

Resource	Specification for Use
	○ After 4 hours or if there is no available space in the room temperature incubator, the system will discard the card in the waste drawer ○ Do not manually add partially used cards to the system. Partially used cards, may be used for manual gel testing or quality control.
Liquids	• Only fill containers with liquids at room temperature.
	• Liquids should not be agitated in a manner that could cause bubbles in the liquid.

- Resources are tracked, monitored, discarded, and replenished using the Vision Resource Screen and the ***Ortho Vision Daily Resource Tracking*** form
- On-Board management of resources is managed via the **Resources Screen**

  - Use touch buttons located on the right side of the screen to display information about each resource – refer to **Appendix 1: Resource Screen Access and Use**
  - Use touch buttons located in the horizontal bar at the bottom of each screen to act or prompt on the data displayed on the screen – refer to **Appendix 2: Resource Action Buttons**
  - ***Ortho Vision Daily Resource Tracking*** form is used to track lot number and expiration of reagents that are not captured and monitored by the analyzer.

SPECIMEN REQUIREMENTS:
N/A

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
• AlbaQ-Check™ Simulated Whole Blood Controls • IgG Sensitized Red Blood Cells ALBAcyte® • C3 Coated Red Blood Cells • 0.8% AFFIRMAGEN® Reagent Red Blood Cells • 0.8% SURGISCREEN® Reagent Red Blood Cells • ID-MTS® Diluent 2 • ID-MTS® Diluent 2 Plus • ID-MTS® Gel Cards	• 10 x 75 glass tubes • 12 x 75 glass or plastic tubes • Evaporation caps • Dilution trays • Applicator sticks • Transfer pipettes • Sample racks	• Ortho Vision

QUALITY CONTROL: QC is performed daily

INSTRUCTIONS:

TABLE of CONTENTS

Printing Barcoded Labels for QC Samples
Preparing 0.8% IgG and C3 Positive Controls Samples
Loading Controls Samples
Running Quality Control
Programming New QC Control Sample ID or Lot Numbers
QC of different ID-MTS Gel Card lots or Reagent Red Cell Lots
Managing Failed QC Results
Printing QC Result Reports
Clearing Multiple Profile QC Lines (Key Operators Only)
Appendix 1: Resource Screen Access and Use
Appendix 2: Resource Action Buttons

Printing Barcoded Labels for QC Samples

STEP	ACTION
1	Log into SmarTerm
2	Enter the appropriate entry when prompted **Prompt** / **Enter** Function / BAR Which medical center (H or U)? / U
3	Press the down arrow key to move the prompt to "Custom Barcodes" and press <Enter>

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>4</td><td>Enter the appropriate entry when prompted
<table>
<tr><th>Prompt</th><th>Enter</th></tr>
<tr><td>Enter device or valid printer #</td><td>14</td></tr>
</table></td></tr>
<tr><td>5</td><td>Press <Enter> to select the UWMC TSL (686) printer</td></tr>
<tr><td>6</td><td>Enter the text for the appropriate specimen label:
<table>
<tr><th>If performing QC for MTS® Gel card</th><th>Enter the following</th></tr>
<tr><td>MTS® Anti-IgG, - C3d Polyspecific Card
and/or
MTS® Anti-IgG Card for DAT IgG</td><td>• IgG C3 NEG
• IgG POS
• C3 POS</td></tr>
</table></td></tr>
<tr><td>7</td><td>Press <Enter> 3 times</td></tr>
<tr><td>8</td><td>Enter the appropriate entry when prompted
<table>
<tr><th>Prompt</th><th>Enter</th></tr>
<tr><td>Do you want sequential labels</td><td>N</td></tr>
<tr><td>Which medical center (H or U)?</td><td>U</td></tr>
<tr><td>Enter number of labels to print</td><td>1</td></tr>
<tr><td>Is this correct</td><td>Y</td></tr>
</table></td></tr>
<tr><td>9</td><td>Repeat steps 2 thru 8 to print additional QC sample labels</td></tr>
<tr><td>10</td><td>Affix the label to the appropriate QC sample container (tube)in a manner allowing scanning by the Vision</td></tr>
</table>

Preparing 0.8% IgG and C3 Positive Controls Samples

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Dispense 2 mL of MTS Diluent 2 into a clean test tube

NOTE: The 2 mL sample will be used in steps 4 & 8 below</td></tr>
<tr><td>2</td><td>Label 10 x 75 mL test tube with the appropriate label in a manner that allows the barcode to be read by the analyzer – refer to section Printing Barcoded Labels for QC Samples
<table>
<tr><th>If preparing</th><th>Then label tube with</th></tr>
<tr><td>IgG positive red cell suspension</td><td>IgG POS label</td></tr>
<tr><td>C3 positive red cell suspension</td><td>C3 POS label</td></tr>
</table></td></tr>
<tr><td>3</td><td>Add 200µL of sensitized cells to the labeled tube
<table>
<tr><th>If preparing</th><th>Add</th></tr>
<tr><td>IgG positive red cell suspension</td><td>IgG sensitized cells</td></tr>
<tr><td>C3 positive red cell suspension</td><td>C3 sensitized cells</td></tr>
</table></td></tr>
</table>

STEP	ACTION
4	Add 100µL of MTS Diluent 2
5	Mix gently to resuspend
6	Centrifuge at wash setting
7	Decant the supernatant
8	Add 400µL of MTS™ Diluent 2 to each tube
9	Gently mix to re-suspend avoiding bubbles or foaming
10	Record the following on the label: • Date prepared • Time prepared • Tech ID

Loading Controls Samples

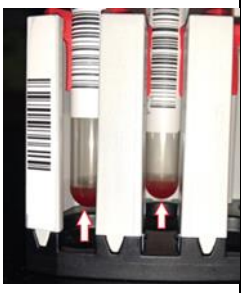
STEP	ACTION
1	**Record** the lot number and expiration date for the following on the ***Ortho Vision Daily Resource Tracking*** form: • AlbaQ-Chek Control samples • IgG Check Cells • C3 Check Cells • 0.8% Affirmagen A1 & B • 0.8% Surgiscreen 1, 2, 3

2	**If Vials** / **Then**
	Were previously opened / Go to next step
	Are from a new AlbaQ-Chek kit / • Place a **IgG C3 NEG** barcoded label on Vial 4 in a manner that allows the barcode to be read by the analyzer - refer to section **Printing Barcoded Labels for QC Samples**
	• Record the following on each vial
	  ○ Open date
	  ○ Expiration date: Samples expire within 7 days or the original expiration date, whichever is shorter
	  ○ Tech ID

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>3</td><td>
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Vials were previously centrifuged and red cells and plasma is separated</td><td>Go to next step</td></tr>
<tr><td>Opening a new kit
or
Red cells and plasma are not separated</td><td>Centrifuge all 4 vials in the kit to separate the red blood cells and plasma in the same manner as patient samples</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Gently mix IgG POS and C3 POS control samples to resuspend cells</td></tr>
<tr><td>5</td><td>Ensure contents of all control samples have warmed to room temperature prior to loading on the analyzer</td></tr>
<tr><td>6</td><td>Remove caps from control samples

NOTE: Cap colors on AlbaQ-Chek samples match the number color on each vial</td></tr>
<tr><td>7</td><td>Load the QC samples into the appropriate rack
<table>
<tr><th>Control Sample</th><th>Load into</th></tr>
<tr><td>AlbaQ-Chek sample</td><td>• Blue rack, S13B with barcodes facing out</td></tr>
<tr><td>IgG POS
and
C3 POS</td><td>• Red rack, S10B with barcodes facing out
• Leave about half an inch between the tubes and the bottom of the rack, so that the tubes do not rest all the way down.

NOTE: This ensures the probe is able to reach the small volume of sample

  </td></tr>
</table>
</td></tr>
</table>

Running Quality Control

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>
<table>
<tr><th>If performing QC on</th><th>Then</th></tr>
<tr><td>New lot number for any reagent</td><td>Go to section Programming New QC Sample Lot Numbers</td></tr>
<tr><td>Previously QC’d lot number</td><td>Go to next step</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>2</td><td>Load the following reagents into the appropriate racks
<table>
<tr><th>Reagent</th><th>Rack</th></tr>
<tr><td>• MTS Diluent 2 Plus
• MTS Diluent 2</td><td>Diluent Rack- N02B</td></tr>
<tr><td>• 0.8% AFFIRMAGEN® Reagent Red Blood Cells
• 0.8% SURGISCREEN® Reagent Red Blood Cells</td><td>Red Cell Reagent Rack-R10B</td></tr>
</table>
NOTE: All reagents must be at room temperature prior to testing</td></tr>
<tr><td>3</td><td>Touch <QC> menu button</td></tr>
<tr><td>4</td><td>Select the QC Test Profile to process – refer to Table 1: MBC QC Test Profiles, Reagents, QC Samples</td></tr>
<tr><td>5</td><td>Touch <Run QC Job> action button</td></tr>
<tr><td>6</td><td>Touch <Save></td></tr>
<tr><td>7</td><td>Touch <Start></td></tr>
<tr><td>8</td><td>Repeat steps 3-7 to select additional test profiles</td></tr>
<tr><td>8</td><td>Touch <Samples> then select a ring position into which samples will be loaded</td></tr>
<tr><td>9</td><td>Touch <Load/Unload> and open the door</td></tr>
<tr><td>10</td><td>Select any additional ring positions into which QC samples will be loaded</td></tr>
<tr><td>11</td><td>Place rack(s) in the Load Station and close the door

NOTE: The system will automatically start running the QC as STAT samples once programmed and loaded it will also auto accept results and archive them.</td></tr>
</table>

Programming New QC Control Sample ID or Lot Numbers

STEP	ACTION
1	Verify no samples are running or results waiting to be archived
2	Touch <QC> menu button

STEP	ACTION
3	Select the QC Test Profile for which the QC Sample is associated - refer to **Table 1: MBC QC Test Profiles, Reagents, QC Samples**
4	Touch <Run QC Job> action button
5	Touch <Change Ortho QC sample ID>
6	Delete the existing number in the sample ID (lot number) Note: To see what QC samples are run with each profile refer to the QC Profiles Table
7	Scan in the new sample ID (lot number) for each sample used for the QC Test Profile – refer to **Table 1: MBC QC Test Profiles, Reagents, QC Samples** **IMPORTANT:** Entering the barcode using the handheld barcode scanner will automatically enter the number twice. If manually typing in the lot number, type the barcode twice.
8	Touch <Save>
9	Repeat steps 2-8 to program additional QC Sample ID (lot number)

QC of different ID-MTS Gel Card lots or Reagent Red Cell Lots

STEP	ACTION	
1	Load all resources including all lots requiring QC	
2	Touch <QC> menu button	
3	Touch <Run QC Job> action button	
4	**If new lot of**	**Then**
	Red cell reagent	• Touch a reagent lot for the reagent type • Touch twice to view all lot numbers that are loaded the analyzer **NOTE**: If there is more than one reagent lot loaded on the analyzer, the default selection is the lot that was most recently registered.
	ID-MTS Gel Card	• Touch a card lot for each required card type • Touch the card type twice to view all lots that are loaded on the analyzer. **NOTE:** If there is more than one required card lot loaded on the analyzer, the default selection is the lot that was most recently registered.

Managing Failed QC Results

STEP	ACTION
1	Select the failed QC sample **If** / **Then** Failure is due to reason that does not affect the result (ie: dust on the card) → • Modify the result and accept the results. Refer to SOP *Ortho Vision® Results Management* QC should be repeated → • Reject the failed QC sample profile • Go to Step 3 **NOTE:** If only one sample of a QC Test Profile fails, only the sample that failed needs to be repeated
2	Touch <Run QC Job> **NOTE:** The failed QC run will remain on the MBC QC Profile list as failed
3	Touch <Save>
4	Touch <Start>

Printing QC Result Reports

STEP	ACTION
1	Touch <QC> menu button
2	Touch the MBC Test Profile Name **NOTE**: Each profile needs to be individually printed
3	Touch <Show QC History Report>
4	Touch <Presets>
5	Touch <Today> and <OK> to display the report
6	Touch <Print>
7	Review the report to verify QC is acceptable
8	Record the following at the bottom of the report: • Date of Review • Tech ID
9	Repeat steps 1 thru 8 for additional Test Profile QC results

Clearing Multiple Profile QC Lines (Key Operators Only)

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Verify no samples are running and that there are no results waiting to be archived

NOTE: Profiles cannot be cleared while samples are running, or results are pending</td></tr>
<tr><td>2</td><td>Touch <Stop Processing> twice</td></tr>
<tr><td>3</td><td>Touch <Setup> and <Testing></td></tr>
<tr><td>4</td><td>• Touch <Grouping Tests into profiles> tab
• Touch <Show Details>

NOTE: A list of all the testing profiles is displayed; only the tests listed as MBC (Method Based Control) need to be reprogrammed with each new lot.</td></tr>
<tr><td>5</td><td>Touch the desired profile (it should be highlighted in white)</td></tr>
<tr><td>6</td><td>Touch <Show QC Samples></td></tr>
<tr><td>7</td><td>• Touch the QC sample to delete
• Touch <Delete Selected>
• Repeat until all necessary QC Samples are deleted</td></tr>
<tr><td>8</td><td>• Touch <Create QC Sample></td></tr>
<tr><td>9</td><td>• Touch QC sample type and select either:
o Ortho QC Sample
▪ Type and Screen Test Profile
▪ Donor Rh Pos Test Profile
▪ Donor Rh Neg Test Profile
o User defined QC sample
▪ DAT Poly Test Profile
▪ DAT IgGTest Profile</td></tr>
<tr><td>10</td><td>
<table>
<tr><th>If using</th><th>Then</th></tr>
<tr><td>Ortho QC sample</td><td>Touch <Ortho QC Sample ID> and scan barcode, sample information will auto populate
<table>
<tr><th>Test</th><th>Sample Type</th><th>Liquid Type</th><th>Expected Results</th></tr>
<tr><td>Type and Screen</td><td rowspan="3">Ortho QC Sample</td><td rowspan="3">AlbaQ-Chek</td><td rowspan="3">Will auto populate</td></tr>
<tr><td>Donor Rh Pos</td></tr>
<tr><td>Donor Rh Neg</td></tr>
</table></td></tr>
<tr><td>User defined QC sample</td><td>• Touch <1st sample ID> and scan barcode
• Touch <1st Sample Liquid Type> and select according to the liquid type listed below
• Touch <Expected Results> and select result according to expected results listed below</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td></td><td>
<table>
<tr><th>DAT Poly Test</th><th>Liquid Type</th><th>Expected Results</th></tr>
<tr><td>IgG C3 NEG</td><td>CentBlood</td><td>NEG</td></tr>
<tr><td>IgG POS</td><td>0.8% cells</td><td>POS</td></tr>
<tr><td>C3 POS</td><td>0.8% cells</td><td>POS</td></tr>
<tr><th>DAT IgG Test</th><th>Liquid Type</th><th>Expected Results</th></tr>
<tr><td>IgG C3 NEG</td><td>CentBlood</td><td>NEG</td></tr>
<tr><td>IgG POS</td><td>0.8% cells</td><td>POS</td></tr>
</table>
</td></tr>
<tr><td>11</td><td>For Ortho Defined QC Sample

Note: For expected results for each AlbaQ-Chek samples go to: Result Interpretation in tests with AlbaQ-Chek and Routine Blood Bank Reagents</td></tr>
<tr><td>12</td><td>Follow these steps to clear each old lot Profile QC line when a new lot of cards/reagents/diluents or other is introduced to the system</td></tr>
</table>

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES
NA

EXPECTED RESULTS:
Type and Screen Test Profile

MTS™ A/B/D Monoclonal and Reverse Grouping Card								MTS™ Anti-IgG Card			
ABO/Rh		Anti-A	Anti-B	Anti-D	Ctrl	A_1 Cells	B Cells	Antibody Detection	SC 1	SC 2	SC 3
QC1	Expected Results	3-4	0	0	0	0	3-4	Expected Results	3-4	3-4	0
QC2	Expected Results	0	0	3-4	0	3-4	3-4	Expected Results	0	3-4	3-4
QC3	Expected Results	0	3-4	3-4	0	3-4	0	Expected Results	0	0	0
QC4*	Expected Results	3-4	3-4	3-4	0	0	0	Expected Results	0	0	0

***** QC4 is not routinely used for QC of the Type and Screen Test Profile.

Donor Rh Neg Test Profile

MTS™ A/B/D Monoclonal Grouping Card				
ABORh		Anti-A	Anti-B	Anti-D
QC1	Expected Results	3-4	0	0
QC3	Expected Results	0	3-4	3-4

Donor Rh Pos Test Profile

MTS™ A/B Monoclonal Grouping Card			
ABO		**Anti-A**	**Anti-B**
QC1	Expected Results	3-4	0
QC3	Expected Results	0	3-4

DAT Poly Test Profile

MTS™ IgG,-C3d Polyspecific Card		
Poly DAT		**IgG,-C3d**
IgG POS	Expected Results	3-4
C3 POS	Expected Results	3-4
QC4	Expected Results	0

DAT IgG Test Profile

MTS™ IgG Card		
IgG DAT		**IgG**
IgG POS	Expected Results	3-4
QC4	Expected Results	0

CALIBRATION:
NA

PROCEDURE NOTES AND LIMITATIONS:
- An Onboard Inventory Report may be printed to assist in performing and verifying QC:
    - Touch <Resources>
    - Touch <Overview>
    - Touch <Show Inventory Log>
    - Touch <Print>
- Biohazard material is disposed of according to local regulations and University of Washington Medical Center guidelines
- The user is responsible for monitoring the length of time the reagents have been on board the analyzer – refer to ***Ortho Vision Daily Resource Tracking*** form
    - Control reagents used for testing, including anti-D, are consistent with manufacturer's instructions

- When using automated instruments, refer to the limitations contained in the operator's manual provided by the device manufacturer. Strict adherence to the procedures and recommended equipment is essential.
- Proper centrifuge calibration is particularly important to the performance of the ID-MTS™ Gel Test. The ORTHO™ Workstation and ORTHO VISION™ Analyzer have been exclusively designed to provide the correct time, speed, and angle.
- Hemolyzed and grossly icteric blood samples may cause difficulty in interpretation, and test results should be used with caution. Occasionally, specimens showing incomplete clotting or excess particulates may need to be washed prior to testing
- Make sure to select the proper sample type before proceeding. Selecting an incorrect sample type may cause incorrect results.
- When a 2nd MLS is not available to perform the review and patient or unit test results must be reported, the MLS tech will independently review the QC results to verify acceptability of result prior to reporting patient testing
- False positive or false negative test results may occur from bacterial or chemical contamination of test materials, aged or hemolyzed blood specimens, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples.
- Antibodies to preservatives, medications, disease states, Wharton's jelly, and/or cross-contamination of reaction microtubes may cause false positive reactions.
- False positive results may occur if a card that shows signs of drying is used in testing.
- Red blood cells must be diluted to 4% ± 1% in MTS™ Diluent 2 *PLUS* before addition to the microtubes of MTS Gel cards for AB, ABD, or ABO/Rh testing.
- Red blood cells must be suspended in MTS™ Diluent 2 or be a commercial 0.8% red blood cell in a low ionic strength diluent specifically approved for use in the ID-Micro Typing System™ to be used with MTS IgG or MTS Anti-IgG, -C3d gel cards.
- Some weak subgroups of the A and B antigen may not be detected by these MTS™ Anti-A and Anti-B reagents. The use of the MTS™ Monoclonal Anti-A,B Card may better detect these weak antigens.
- Variations in red blood cell concentration can markedly affect the sensitivity of test results. If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in the antigen/antibody ratio. In addition, cells may fail to completely migrate to the bottom of the microtube and could cause a false positive interpretation. When red blood cells are too low in concentration, they become difficult to visualize and, in extreme cases, a weak positive can fail to be detected.
- Rouleaux caused by serum or plasma with abnormally high concentrations of protein (such as in patients with multiple myeloma or Waldenstrom's macroglobulinemia or from patients who have received plasma expanders of high molecular weight) may infrequently cause difficulties in ID-MTS™ Gel Test interpretation, false positive results or hazy reactions may occur with these samples but are rare. If false positive reactions (e.g., rouleaux, cells coated with immunoglobulins, etc.) occur in the control gel, the blood group cannot be established. Additional testing will be necessary to resolve this false positive reaction. Refer to SOPs-*ABO/Rh Discrepancy* and *Saline Replacement*.
- Suppressed or diminished expression of certain blood group antigens may give rise to false negative reactions. For this reason, caution should always be exercised when assigning the ABO phenotype. The results of forward grouping (red blood cell) testing should be confirmed by reverse grouping (serum) testing.
- In some patients (e.g., newborns, elderly or immunocompromised patients) the expected ABO antibodies may be weak or missing. For any recipient whose ABO group cannot be

accurately determined, group O red blood cells should be considered as a transfusion alternative. The interpretation of reactions obtained when testing infant blood may be complicated by the fact that the infant's serum does not necessarily contain antibody for any antigen absent from the cells, and passive anti-A and/or Anti-B from the mother's circulation may yield conflicting reactions when tests are performed on cord blood specimens. Cord blood specimens may also give weaker than normal reactions in the cell grouping test. Imperfect development of the ABH antigens at birth may lead to false negative results, particularly with Anti-A reagents.

- When using automated instruments, refer to the limitations contained in the operator's manual provided by the device manufacturer
- Anomalous results may be caused by fibrin or other particulate matter in blood samples that could stick to the sides of the microtube during ABO/Rh testing. .
- 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 of MTS IgG or MTS Anti-IgG, -C3d gel cards. Anomalous results (i.e., a line of red blood cells on the top of the gel) may be observed with serum samples and can be minimized with the use of EDTA plasma
- The MTS™ Anti-IgG Card is not manufactured to detect Anti-C3 cell sensitizations. It may be used in the compatibility test; however, some literature reports indicate that the Anti-IgG may occasionally fail to detect antibodies that are demonstrable using antiglobulin reagents containing Anti-C3.
- There is the potential for IgM antibodies to react to anti-IgG testing. Some patient antibodies that are IgM in nature may react with corresponding antigens in the upper portion of the microtube and be trapped in the top portion of the gel at the time of centrifugation resulting in a positive reaction.
- Negative direct antiglobulin test results do not necessarily rule out hemolytic disease of the newborn (HDN), especially if ABO incompatibility is suspected.

REFERENCES:

- ORTHO VISION® Analyzer Procedure Pub. No. J56102
- ORTHO VISION® Analyzer General Operator Training Manual
- AlbaQ-Chek™ Simulated Whole Blood Controls Package Insert
- Antibody Identification Method (with Auto Control) Using MTS™ Anti-IgG Cards

RELATED DOCUMENTS:

FORM Ortho Vision Daily Resource Tracking

APPENDICES:

Appendix 1: Resource Screen Access and Use

Resource	To access	Use
Reagents	Reagents Screen • Touch <Resources> • Touch <Reagents>	To evaluate current inventory of reagents loaded on the system and manage reagent lots
	Load/Unload button • Touch <Show Details> while in Table View	Loading and unloading reagents as needed
Reagents Lots	Reagent Lot information • Touch <Resources> • Touch <Reagent Lots>	To register lots and view information about reagent kits. Information displayed may include • Lot # • Expiration Date • Onboard reagents • QC status if applicable • Reagent Kit – The name of the reagent kit or reagent family associated with the lot
Dilution Trays	Dilution Trays screen • Touch <Resources> • Touch <Dilution trays>	To view information about the availability and position of dilution wells
Cards	Cards screen • Touch <Resources> • Touch <Cards>	To view: • Card carton position and other associated information, such as location and lot expiration dates • Card type, errors and warnings
Waste	Waste screen • Touch <Resources> • Touch <Waste>	To view the current status of the waste drawer, card waste drawer and liquid waste bottle. Information displayed includes: • Total Capacity – Available fill level • Current Capacity – Free fill level • Time Until Full – An expected fill level and estimated time until the fill level is reached.
Liquids	Liquid screen • Touch <Resources> • Touch <Liquids>	To monitor the availability of deionized water and saline on the system.
Manual Load/Review	Manual Load/Review • Touch <Resources> • Touch < Manual Load/Review	To view the status of tests on the system requiring manual review. **NOTE:** This screen only provides access to the manual review function. It does not allow use of the LOAD AREA in the DUAL PURPOSE DRAWER.

Appendix 2: Resource Action Buttons

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.
	Show Usage Statistics	Displays information about used/unused consumables. Number of orders failed/finished. Number of tests started/reportable/finished/failed. Number of test result started/indeterminate/finished/failed

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	

REVISION: Change the ID# of the barcode sticker printer, removal of phenotyping, added statement anti-D controls meet manufacturer's requirements