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-0070.01

TITLE: **Ortho Vision® Results Management**

PURPOSE:
To define the procedure for reviewing and transmitting results from Ortho Vision® to the Laboratory Information System (LIS)

PRINCIPLE & CLINICAL SIGNIFICANCE:
Accuracy of test results requires the operator to visually review flagged test results and reject any unacceptable results prior to transmission to the LIS. The results must be reviewed for acceptability and correct interpretation in LIS prior to completion of test. Users accepting and resulting test results must be familiar with the test principles and fully trained and competent to interpret the results.

POLICIES:
- Ortho Vision® will automatically send test results to the LIS if there are no test results flagged for review.
- Ortho Vision® results flagged for review must be manually reviewed and accepted prior to sending results to LIS. Once results are accepted, results can no longer be edited.
- The following will be flagged by Ortho Vision® and require manual review;
    - Any maintenance task not completed successfully
    - Abnormalities in gel columns (ie: bubbles)
    - Unexpected reactions not predefined as acceptable (ie: rouleaux, hazy or pink gel color due to hemolysis)
    - Discrepant results of the same test assay within the same order
    - Pattern of reactions do not match predefined interpretations
    - See Procedure Notes for additional reason a result may be flagged for review
- All transmitted test results must be reviewed for accurate interpretation prior to accepting test result in LIS. The final interpretation in LIS must be reported per appropriate test assay procedure.
- The LIS Interface should be cleared at least once per shift or as needed in order to maintain functionality and clear any undesired results.

SPECIMEN REQUIREMENTS:
N/A

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
N/A	ID-MTS Cards	Vision

QUALITY CONTROL: Quality Control is performed each day of use

INSTRUCTIONS:

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Test Results Review

STEP	ACTION
1	Touch Results menu button to view, review and monitor test results 
2	**If results have been** / **Then** Completed and sent to LIS automatically / Go to Section *Interpretation and Result Reporting in LIS* Flagged for manual review – See Appendix 2: for description of code and suggested actions / Go to next step
3	**If MTS Gel Card is** / **Then** Available to review / Go to next step Not available to review / Go to step 7
4	Touch the <Resources> menu button 
5	Touch <Manual Load/Review> action button
6	Touch the <Load/Unload> action button to retrieve cards from the dual purpose drawer

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>7</td><td>Open the Dual Purpose Drawer when unlocked</td></tr>
<tr><td>8</td><td>Retrieve the card from the rack</td></tr>
<tr><td>9</td><td>Select the test result that requires review from the Results menu</td></tr>
<tr><td>10</td><td>Touch the <Show Details> action button  Image of the test result card will be displayed</td></tr>
<tr><td>11</td><td>Review the test result and gel card
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Column reaction grade needs to be edited</td><td> 
• Touch <Edit Grades> action button
• A wizard opens
• Scan the barcoded ID of the gel card with the grade you wish to edit - the last 5 digits of the card ID are displayed in the upper left hand corner of the gel card picture
• Touch the grade for the column that you wish to edit – alternative grades will display
• Select the appropriate grade
• Touch <Next> to add a comment describing the reason for change
• Touch <Next>
• Enter your password and touch <Confirm Password></td></tr>
<tr><td>Test interpretation needs to be edited</td><td> 
• Touch <Edit Grades> action button
• Three screen wizard opens
• Select the result you wish to edit
• Select the correct result
• Touch <Next> to add a comment describing the reason for change
• Touch <Next>
• Enter your password and touch <Confirm Password></td></tr>
<tr><td>No Result Interpretation</td><td>• Verify reactions in columns are correct

NOTE: Reaction results can be sent across after review to the LIS for result interpretation</td></tr>
</table></td></tr>
<tr><td>12</td><td><table><tr><th>If Test result is</th><th>Then</th></tr></table></td></tr>
</table>

STEP	ACTION	
	Acceptable	 • Touch the <Accept Result> action button **CAUTION:** Once a result is accepted it cannot be edited • The status will change to “Accepted” in the status window on the Details screen  • Touch the Send to LIS button
	Not Acceptable	 • Touch the <Reject Result action button **NOTE:** Rejected results can still be edited or accepted • The rejected result icon appears next to this result on the Details screen. • Do **NOT** transmit result to LIS
13	Go to Section Printing Reports to printing test result as needed.	
14	Go to Section *Result Reporting in Sunquest*	

Viewing MTS Gel Card Results on Monitor Screen

STEP	ACTION	
1	Touch <Results>	
2	Select a result – the screen will display an image of the card	
3	Touch <Show Details> action button	
4	**To**	**Then**
	Change card view	• Touch the <Change to Back> action button  • The reverse side of the card is displayed • Touch the <Change to Front> action button to return to the front **NOTE**: The action button switches between Back and Front depending on which view is displayed
	Change image color	• Touch the <Change to Color> action button  • The color image is displayed

STEP	ACTION	
		• Touch the <Change to Grayscale> action button to return to previous view • The action button becomes change to Grayscale
	Zoom in on the image	• Touch the column you wish to see enlarged • An enlarged view of the column is displayed in color and in grayscale • This view also shows the front and back sides of the column **NOTE**: The action button switches between Back and Front depending on which view is displayed

Adding Result Comments

STEP	ACTION
1	Touch the <Results> menu button
2	Select the result you wish to add a comment
3	Touch <Show Details> action button - card image appears
4	Touch <Show details> action button again and then 
5	Touch <Add comment>
6	Enter the comment
7	Touch <Save>

Printing Reports

STEP	ACTION
1	Touch <Show Order> report button **NOTE:** The Print button becomes available
2	Touch <Print>

Archiving Results Manually

NOTE: Ortho Vision® automatically archives test results after 1 hour.

STEP	ACTION
1	Select the test result to be archive **NOTE:** Vision auto archives test results after 1 hour

STEP	ACTION	
2	Touch t <Archive Order> button **IMPORTANT:** The result will disappear from the screen and it will be no longer be possible to create the order report for it.	

Clearing Interfaced Results

STEP	ACTION	
1	Log into SmarTerm	
2	Enter '**OFC**' at the Function prompt	
3	Enter the instrument code from which results are to be cleared at the Method Code prompt (VIS1 or VIS2)	CLEANUP ONLINE DEVICE FILE Method Code : VIS1 Start at Cup Number <1> : 1 Stop with Cup Number <241> : 241 CLEANUP OF DEVICE VIS1 STARTED FIRST CUP CLEANED = 1 LAST CUP CLEANED = 241 CLEANUP OF DEVICE VIS1 COMPLETED
4	Press <Enter> at the 'Start at Cup Number' prompt	
5	Press <Enter> at the 'Stop with Cup' Number prompt	

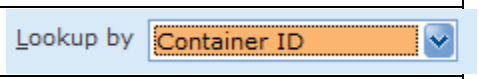
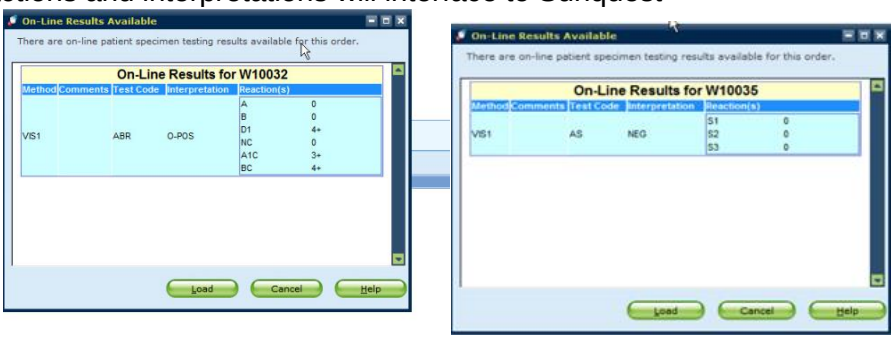
CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES

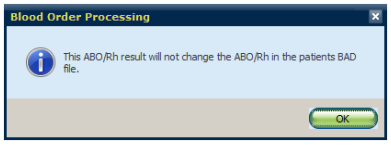
Interpretations:
Refer to the individual test assays ***Grading Reactions*** SOPs for interpreting test results

Test Assay	SOP
ABO/Rh Cord Blood ABO/Rh	• ABO/Rh Manual Gel Method • ABO/Rh Discrepancy Resolution **NOTE:** ○ Reverse grouping is not performed on **cord blood samples** and is resulted as ND in the test grid from the Vision to the LIS ○ Mixed Field (**MF**) reactions are not graded using the MTS gel method • No type determined (**NTD**) interpretations– refer to SOP ABO/Rh Discrepancy Resolution
Antibody Screen	Antibody Screen Manual Gel Method
Donor ABO/Rh Confirmation	Unit Type Confirmation Using Tube Method

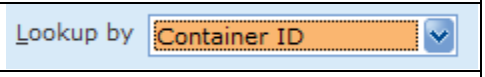
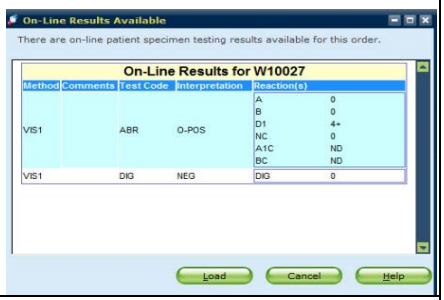
Test Assay	SOP
DAT (poly & IgG)	DAT Manual Gel Method
Antibody Titers	Ortho Vision® Antibody Titration
Rh Phenotype	Ortho Vision® Rh Phenotype

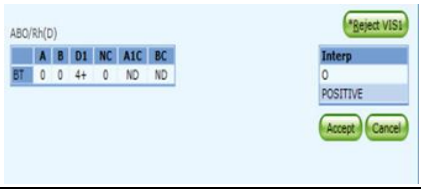
Results Reporting in Sunquest
ABO/Rh and Antibody Screen

STEP	ACTION
1	Open ‘Blood Order Processing’ in Sunquest
2	Select ‘Container ID’ from the Lookup by menu 
3	Scan the CID label on the sample with pending results acceptance in Sunquest
4	Click <Search> or press <Enter> to select the correct sample
5	Click <Select> or press <Enter> to enter the accession
6	Click the <Patient Specimen> tab
7	Click <Load> on the ‘On-Line Results Available’ window to populate the results – Test reactions and interpretations will interface to Sunquest 
8	**If** / **Then** Accepting results: • Click <Accept> **NOTE**: Results with valid interpretation does not need to be accepted Rejecting results: • Click <Reject> • Enter interpretation for results 

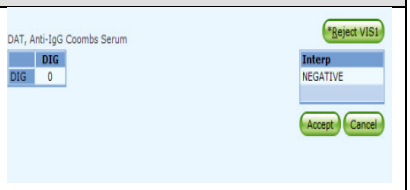
STEP	ACTION	
9	**If results**	**Then**
	Matches the patient's historical ABO/Rh or no historical record exits	Click the <Save> button **NOTE:** If the antibody screen is positive, refer to the SOP *Antibody Screen Testing* to determine if antibody identification is required
	Does not match the historical record	• Click <OK> to clear the message displayed below  • Make a printscreen of the discrepant results • Click <Cancel> to clear the results • Refer to SOP *ABO/Rh Discrepancy Resolution* and *Weak D Tesing* to resolve the discrepancy

Cord Blood ABO/Rh and IgG DAT

STEP	ACTION	
1	Open 'Blood Order Processing' in Sunquest	
2	Select 'Container ID' from the Lookup by menu	
3	Scan the CID label on the sample with pending results acceptance in Sunquest	
4	Click <Search> or press <Enter> to select the correct sample	
5	Click <Select> or press <Enter> to enter the accession	
6	Click the <Patient Specimen> tab	
7	Click <Load> on the 'On-Line Results Available' window to populate the results	
8	**If**	**Then**
	Accepting results	• Click <Accept> **NOTE**: Results with valid interpretation does not need to be accepted



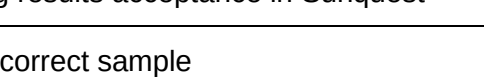
STEP	ACTION	
	Rejecting results	• Click <Reject> Enter interpretation for results

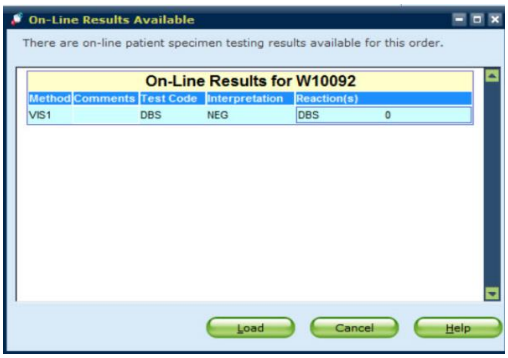


9	If the test results are	Then	
	Acceptable	Click the <Save> button	
	Not acceptable	• Do not accept and save test results and interpretation • Refer to SOP ABO/Rh Discrepancy Resolution and *Weak D testing* to resolve the discrepancy	

Poly and IgG DAT

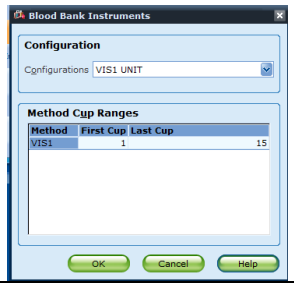
STEP	ACTION
1	Open 'Blood Order Processing' in Sunquest
2	Select 'Container ID' from the Lookup by menu
3	Scan the CID label on the sample with pending results acceptance in Sunquest
4	Click <Search> or press <Enter> to select the correct sample
5	Click <Select> or press <Enter> to enter the accession
6	Click the <Patient Specimen> tab
7	Click <Load> on the 'On-Line Results Available' window to populate the results

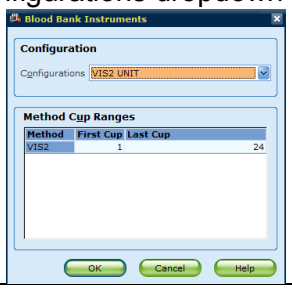


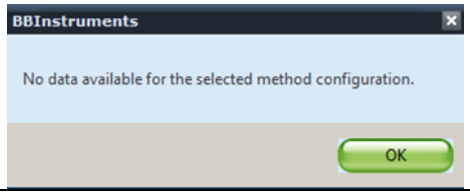
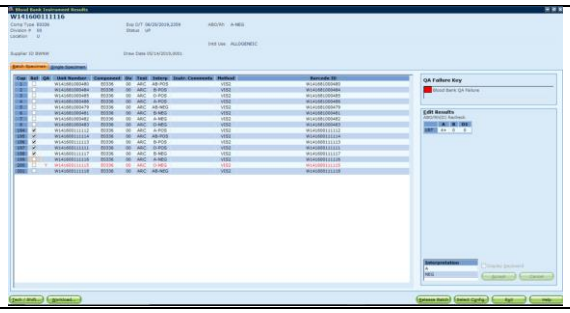


9	**If the test results are**	**Then**
	Acceptable	Click the <Save> button
	Not acceptable	• Do not save test results and interpretation • Refer to SOP *DAT by Tube Method* to resolve discrepancy

Donor ABO/Rh Confirmation

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>
<table>
<tr><th>If your ‘Blood Bank Instrument’ module</th><th>Then</th></tr>
<tr><td>Is configured to accept donor ABO/Rh reconfirmations</td><td>Go to next step</td></tr>
<tr><td>Is NOT configured to accept donor ABO/Rh reconfirmations</td><td>Go to Appendix 1: Blood Bank Method Configuration Set Up</td></tr>
</table>
</td></tr>
<tr><td>2</td><td>Open ‘Blood Bank Instruments’ in Sunquest</td></tr>
<tr><td>3</td><td>Select “VIS1 UNIT” or “VIS2 UNIT” from the Configurations dropdown
 


</td></tr>
<tr><td>4</td><td>Click <Ok>

NOTE: Cup error will appear for any pending cup results that have not been cleared – refer to section Clearing Interface Results</td></tr>
<tr><td>5</td><td>Click <Ok> through any error messages</td></tr>
<tr><td>6</td><td>Blood Bank Instrument results screen appears.
<table>
<tr><th>If there are</th><th>Then</th></tr>
<tr><td>No test results available</td><td>The following message appears
 
</td></tr>
<tr><td>Test results are available</td><td>Go to next step</td></tr>
</table>
</td></tr>
<tr><td>7</td><td>Use the Batch Specimen Mode to accept the results</td></tr>
<tr><td>8</td><td>Verify the following
• Unit number
• LIS blood type
• Vision test result and historical blood type</td><td>  </td></tr>
</table>

STEP	ACTION	
9	**If Result is**	**Then**
	Not Discrepant	• Check the box in the Release column for each component with acceptable results • Select “Release Batch” button **NOTE:** Once released, the following message appears ‘All released instrument data filed successfully.’ • Select the ‘OK’ button.
	Discrepant	• Result will be displayed in red. The QA column will display “Y” indicating override is needed. • Do not check the box • Do not release unit to available inventory • Go to Section: ***Clearing Interface Results*** to clear result

CALIBRATION:
N/A

PROCEDURE NOTES AND LIMITATIONS:
- Results that are above or below the reportable range will be flagged. If the result has been flagged, the information listed below is shown:
  - Accepted/Rejected
  - Transferred to LIS
  - Instrument simulated
  - Result edited by user
- In addition, the flags listed below require a manual review of the result (refer to Appendix 2 for code descriptions and suggested actions):
  - Result expired
  - Errors from imaging system
  - QC expired
  - Lot expiration
  - Sensor reading temperature dropping out of the notification range
  - Sensor reading humidity dropping out of the notification range
  - Maintenance expired/failed
  - Edited results
- Edits to reaction grading may only be performed prior to transmitting results from the Vision to the LIS
- The Dual Purpose Drawer (manual load/review area) should be checked periodically to clear any pending results due to the limited capacity for 10 cards

REFERENCES:
Ortho Vision Reference Guide
Sunquest Mysis 8.1

RELATED DOCUMENTS:
ABO/Rh Manual Gel Method
SOP ABO/RH Discrepancy Resolution
SOP Weak D Testing
SOP Sample Acceptability
SOP Antibody Screen Manual Gel Method
SOP DAT Manual Gel Method
SOP Ortho Vision® Antibody Titration
SOP Ortho Vision® Rh Phenotype
SOP Ortho Vision Quality Control and Resources
SOP Grading Reactions
SPO Unit Type Confirmation Using Tube Method

APPENDIX:

Appendix 1: Blood Bank Method Configuration Set Up

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Open Blood Bank Method Configuration

NOTE: Individual users will need to set up for each PC that will be used in TSL to report results using Blood Bank Instruments</td></tr>
<tr><td>2</td><td>Click configuration dropdown box</td></tr>
<tr><td>3</td><td>Type “VIS1 UNIT” and the following options appears
<table>
<tr><th>Options</th><th>Select</th></tr>
<tr><td>Patient/Product</td><td>Product</td></tr>
<tr><td>View</td><td>Batch</td></tr>
<tr><td>Cups</td><td>Unreviewed only</td></tr>
<tr><td>Methods & Tests</td><td>
<table>
<tr><th>Option</th><th>Select</th></tr>
<tr><td>Methods</td><td>VIS1 or VIS2</td></tr>
<tr><td>Available Test Codes</td><td>%ARC</td></tr>
</table>
</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Click <Save></td></tr>
<tr><td>5</td><td>Repeat steps 2-4 for or VIS2 UNIT</td></tr>
</table>

Appendix 2: Flagged Result Codes

Codes indicate conditions that require operator attention. For example, if a bubble is detected in a column during the post processing check, the result is not reported and the system assigns the code 'BUB" to the result to call attention to the bubble that was detected. The table below displays Result Values (codes). Result Values are shown on the Results screen, printed on reports, and included on Log files. If a result code is frequent, contact Customer Technical Support. Always refer to the Instructions for Use and the Reference Guide for additional information.

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
0	N/A	Negative	N/A	• Follow appropriate Standard Operating Procedure
1+	N/A	Positive	N/A	
2+	N/A	Positive	N/A	
3+	N/A	Positive	N/A	
4+	N/A	Positive	N/A	
U	Unknown	No Result Reported	The system received a result from the IMAGING SYSTEM that was not interpretable.	• Rerun the test.
CNF	Column Not Found	If the correct location could not be ensured during the preprocessing check, the column will be marked as not usable; if the correct location could not be found during the post processing check the result is not reported.	The CARD IMAGING SYSTEM could not ensure the column was in the correct location.	• If the correct location could not be ensured during the preprocessing check, clean any debris from the surface of the card and load the card into the SUPPLY DRAWER to be reused. • If the correct location could not be found during the post processing check, manually read the reaction.
WLL	Wrong Liquid Level	No Result Reported	The IMAGING SYSTEM could not confirm that the correct volume of liquid is in the reaction chamber. One of the liquid additions may be missing.	• Inspect the reaction chamber to determine if the liquid level is correct or not. A false error may be caused by a faint meniscus. • If the liquid level is correct, manually read the column and edit the column result. • If the liquid level is not correct, inspect the sample and reagents. • Remove bubbles or foam before loading tubes and vials onto the instrument. • Review the error screen for liquid flow or liquid level errors that are time related and troubleshoot as necessary. • Rerun the test. • If the error persists, inspect the SYRINGE, DILUTOR VALVE, and TIP TUBING fittings for leaks. Perform the PIPETTE Volume Test to verify metering system integrity.
LTL	Light Too Low	No Result Reported	The light level between the columns is checked	• There may be debris on the card, or there was not enough sample plasma and red blood cells were aspirated instead of

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
			with every read; the adjacent light level read was too low. This may be caused when too many red blood cells were pipetted.	plasma. • If there were too many RBCs in the column, they can block light. • If the result code is intermittent, there may be debris on the card. Clean the debris from the surface of the card and perform a manual read of the column. • Check the sample container and if the plasma has been depleted, rerun the test using a new sample.
LTH	Light Too High	No Result Reported	The light level between the columns is checked with every read; the adjacent light level was too high.	• Inspect the card for holes or reflective debris, and manually read the reaction. • If the result code is frequent, the user may need to clean or adjust the IMAGING SYSTEM.
CI	Contrast Interference	No Result Reported	The liquid in the column above the media was dark and the IMAGING SYSTEM could not confidently interpret the reaction. This can be caused by hemolysis, icterus, turbidity or lipemia.	• Rerun the test, or manually read the reaction.
NC	No Cells	No Result Reported	The IMAGING SYSTEM found that there were no cells or almost no cells in the column.	• There may be insufficient reagent or sample volume. • Confirm there is reagent and sample available and rerun the test.
TFC	Too Few Cells	No Result Reported	The IMAGING SYSTEM determined that there were not sufficient cells in the column for a valid interpretation.	• There may be insufficient reagent or sample volume, or red blood cells may not have been properly suspended. • Check the reagent vials and replace them if necessary. • Rerun the test.
TMC	Too Many Cells	No Result Reported	The IMAGING SYSTEM determined that there were too many cells in the column for a valid interpretation.	• Reagent red blood cells may not have been properly suspended, • RBC reagent may have evaporated, or there was not enough sample plasma and patient RBCs aspirated instead of plasma. • If it is suspected that the reagent red blood cells have been compromised due to improper suspension or evaporation discard all vials from that set and replace with a new set. Resuspend the reagents and rerun the test. • If the user suspects the sample is the source of the TMC code, make sure there is adequate plasma volume and rerun the test. • Recentrifuge the sample if needed.
MF	Mixed Field	No Result Reported	The distribution of the cells within the column indicates that there may be a dual population of cells.	• Manually interpret the reaction; follow appropriate Standard Operating Procedure
?	Indeterminate	No Result Reported	The strength of the reaction or the distribution of the	• Rerun the test or manually interpret the reaction following appropriate Standard Operating Procedure

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
			cells within the reaction prevented the IMAGING SYSTEM from determining whether the reaction was positive or negative.	
FIB	Fibrin	No Result Reported	The IMAGING SYSTEM saw an agglutinate which may have been caused by fibrin in the sample.	• Manually review the card. • Follow instructions for manually reviewing and reporting results and retesting. • Inspect the sample for quality issues. • Follow the appropriated Standard Operating Procedure for sample processing before testing. • Adjust the centrifugation speed and time to achieve the optimal cell/plasma separation. • If the problem persists, call OCD Customer Technical Support.
BUB	Bubble	If a bubble is found during the preprocessing check the column will be marked as not usable; if a bubble is found during the post processing check the result is not reported.	The IMAGAING SYSTEM detected a bubble that was large enough to effect the reaction.	• Rerun the test or manually interpret the reaction following the appropriate Standard Operating Procedure.
FOC	Focus Error	If the focus targets appear to be incorrect in the preprocessing check the card will be marked as not usable; if the focus targets do not look correct during the post processing check the result is not reported.	The focus targets appear to be incorrect to the IMAGING SYSTEM.	• Inspect the focus targets for debris and clean them if necessary.
PE	Position Error	No Result Reported	The IMAGAING SYSTEM has determined that the card is not properly positioned.	• If the result code is intermittent, rerun the test.
CVE	Column Volume Error	If the liquid volume is inadequate during the preprocessing check the column will be marked as not usable.	The liquid volume above the media is inadequate.	• Evaporation of the column liquid may have occurred or the system rejected the card before it was used and automatically ran the test using another card. • Refer to the MTS Card Instructions for Use to determine proper disposition of the Card.
CND	Card Not Detected	No Result Reported	The IMAGING SYSTEM has determined that the card is not properly positioned or is missing.	• If the result code is intermittent, rerun the test.

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	