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-0073.01

TITLE: **Ortho Vision® - Patient and Donor Testing**

PURPOSE:
To provide instructions for loading and ordering test assays for patient and donor testing on the Ortho Vision® Analyzer

PRINCIPLE & CLINICAL SIGNIFICANCE:
ORTHO VISION® Analyzer is an instrument designed to automate in-vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. The 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. The ORTHO VISION® Analyzer is bi-directionally interfaced with the Laboratory Information System (LIS).

The system performance specifications define the performance levels of the ORTHO VISION® analyzer intended to support the available test menu. The actual performance parameters (such as incubation temperature, incubation duration, nominal metered values, etc.) are based on the ID-MTS™ Gel Card Instructions for Use, and are defined and fixed by software configurations. Performance parameters, therefore, respect the method protocols defined in the *ID-MTS™ Gel Card IFUs Instructions for Use*, and are not selectable by the operator.

POLICIES:
- The following assays may be run on the Ortho Vision® Analyzer
  - Type and Screen
  - ABO/Rh
  - Antibody screen
  - Donor Rh Pos
  - Donor Rh Neg
  - DAT Poly
  - DAT IgG
  - Antibody Identification Panel – reactions do not interface to LIS
  - Rh Phenotyping – see SOP *Ortho Vision Rh Phenotyping*
  - Antibody Titers – see SOP *Ortho Vision Antibody Titration*
- The following tests require manual order entry on the Ortho Vision®. These do not download automatically from the LIS
  - Donor Rh Pos/Neg
  - Add on tests – Example: DAT Poly (DBS) added to a Type and Screen (TSCR)
    - Add on test should be added in the LIS prior to loading and running on the Ortho Vision®

- Reagent and diluent required for each test assay are listed in Table 1.

Table 1: Test Assays and Required Reagents & Diluents

Assay	ID-MTS™ Gel Card	Reagents	ID-MTS™ Diluents
Type and Screen	• A/B/D Monoclonal and Reverse Grouping Card • Anti-IgG (Rabbit) Card	• 0.8% AFFIRMAGEN Red Blood Cells • 0.8% SURGISCREEN® Red Blood Cells	Diluent 2 Plus Diluent 2
ABO/Rh	• A/B/D Monoclonal and Reverse Grouping Card	• 0.8% AFFIRMAGEN® Red Blood Cells	MTS Diluent 2 Plus
Antibody Screen	• Anti-IgG (Rabbit) Card	• 0.8% SURGISCREEN® Red Blood Cells	MTS Diluent 2
Antibody ID Panel	• Anti-IgG (Rabbit) Card	• 0.8% ORTHO RESOLVE® Panel Reagent Red Blood Cells	MTS Diluent 2
Donor Rh Pos	• A/B Monoclonal Grouping Card	NA	MTS Diluent 2 Plus
Donor Rh Neg	• A/B/D Monoclonal Grouping Card	NA	MTS Diluent 2 Plus
DAT Poly	• Anti-IgG,- C3d Polyspecific (Rabbit) Card	N/A	MTS Diluent 2
DAT IgG	• Anti-IgG (Rabbit) Card	N/A	MTS Diluent 2

SPECIMEN REQUIREMENTS:

- Specimens must be at room temp before loading
- EDTA is preferred and if not tested soon after collection, should be stored at 2-8°C
- Packed red blood cells (donor specimens)
- Plasma and serum
- Clotted specimens may not be used
- If non-anticoagulated whole blood is used, only the serum may be used
- See SOP *Specimen Acceptability*

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
• ID-MTS™ Diluent 2 • ID-MTS™ Diluent 2 Plus • ID-MTS™ Gel Cards • 0.8 % AFFIRMAGEN® Reagent Red Blood Cells • 0.8% SURGISCREEN® Reagent Red Blood Cells • 0.8% ORTHO RESOLVE® Panel(s) Reagent Red Blood Cells	• Sample Racks	ORTHO VISION

QUALITY CONTROL:

Quality control is performed daily and deemed acceptable before verification of patient or donor test results. Refer to SOP *Ortho Vision® Quality Control and Resources*

INSTRUCTIONS:

TABLE of CONTENTS:

Loading Samples

STEP	ACTION
1	Load samples into appropriate rack according to test and tube size, barcode labels must be facing out

RACK	TUBE SIZE
S10B (red)	10 x 75 mL
S13B (blue)	12 x 75 mL
S44B (blue with silver prongs)	Microtainers
S16B (green)	Large tubes

Test	Rack
Type and Screen	S13B (blue)
ABO/Rh	S13B (blue)
Antibody Screen	S13B (blue)
Donor ABO/Rh confirmation	S10B (red)
Cord Blood Testing	S13B (blue)
DAT Poly	S13B (blue)
DAT IgG	S13B (blue)

STEP	ACTION
2	Touch <Samples>
3	Select a ring position into which you want to load samples 
4	Touch <Load/Unload> and open the door
5	Load Sample Rack
6	Select any additional ring positions into which you want to load samples wait for the rotor to move to the selected position and load the remaining rack(s) **NOTE:** All 6 positions may be loaded
7	Close the Load Station Door and the system will download orders from the LIS and start testing

If the system	Then
Automatically downloads orders form the LIS	The Vision automatically scans sample ID and starts running the assay
Does not download from LIS	

If creating an	Then go to section
Order for a single sample	Creating an Order for a Single Sample
Order with the same profile for multiple samples	Creating a Batch Order

Creating an Order for a Single Sample

NOTE: Refer to Table 1 above for list of reagents required for each assay

STEP	ACTION
1	Touch the sample displayed in yellow with the comment “Loaded no order”. This will highlight the selection in white
2	Touch < Create order> and order settings will display for the sample ID you selected.
3	Fill in the required details for the assay to be run

Assay	Sample Liquid	Assigned Profiles	Sample Priority	Manual Review
Type & Screen	CENTBLOOD	Type and Screen	Routine or Stat	No
ABO/Rh	CENTBLOOD	Blood Type or Type and Screen	Routine or Stat	No
Antibody Screen	PLASMA or CENTBLOOD	Antibody Screen or Type and screen	Routine or Stat	No

STEP	ACTION				
	ABO/Rh Confirmation	PACKED CELLS	Donor Rh Neg or Donor Rh Pos	Routine or Stat	No
	Cord Blood Testing	CENTBLOOD	Cord Blood	Routine or Stat	No
	DAT Poly	CENTBLOOD	DAT Poly	Routine or Stat	No
	DAT IgG	CENTBLOOD	DAT IgG	Routine or Stat	No
	Antibody Panel	CENTBLOOD	ABID Panel A or ABID Panel B	Routine or Stat	No
	Selected Cells	CENTBLOOD	• Select ABID Panel A or B • Select **Disable Assays** • Select cells that will NOT be tested • Cells to be tested will be highlighted in white	Routine or Stat	No
4	Touch <Save and Start>				

Creating a Batch Order

NOTE: Used to create an order with the same profile for multiple samples
NOTE: Refer to Table 1 above for list of reagents required for each assay

STEP	ACTION
1	Touch <Samples>
2	Touch <Batch Order>
3	Touch <Sample ID> and select the sample IDs from the list displayed on the screen **NOTE:** This list will correspond to all sample IDs on board. All samples included in a same batch order have to belong to the same sample type. **NOTE:** <Select all> and <Deselect all> buttons are available
4	Fill in the required details **NOTE:** All the samples selected should have the same sample type, selecting an incorrect sample type may cause incorrect results

Assay	Sample Liquid	Assigned Profiles	Sample Priority	Manual Review
Type & Screen	CENTBLOOD	Type and Screen	Routine or Stat	No
ABO/Rh	CENTBLOOD	Blood Type or Type and Screen	Routine or Stat	No
Antibody Screen	PLASMA or CENTBLOOD	Antibody Screen or Type and screen	Routine or Stat	No
ABO/Rh Confirmation	PACKED CELLS	Donor Rh Neg or Donor Rh Pos	Routine or Stat	No
Cord Blood Testing	CENTBLOOD	Cord Blood	Routine or Stat	No

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<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td></td><td>
<table>
<tr><th>Assay</th><th>Sample Liquid</th><th>Assigned Profiles</th><th>Sample Priority</th><th>Manual Review</th></tr>
<tr><td>DAT Poly</td><td>CENTBLOOD</td><td>DAT Poly</td><td>Routine or Stat</td><td>No</td></tr>
<tr><td>DAT IgG</td><td>CENTBLOOD</td><td>DAT IgG</td><td>Routine or Stat</td><td>No</td></tr>
<tr><td>Antibody Panel</td><td>CENTBLOOD</td><td>ABID Panel A or ABID Panel B</td><td>Routine or Stat</td><td>No</td></tr>
<tr><td>Selected Cells</td><td>CENTBLOOD</td><td>• Select ABID Panel A or B
• Select Disable Assays
• Select cells that will NOT be tested
• Cells to be tested will be highlighted in white</td><td>Routine or Stat</td><td>No</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>Touch <Save and Start></td></tr>
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CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES

Refer to SOP *Ortho Vision® Result Management*

CALIBRATION: NA

PROCEDURE NOTES AND LIMITATIONS:

- Grossly hemolyzed, lipemic, icteric or turbid samples may cause the system to report an error or a discrepant interpretation of the sample.
- Imaging system is extremely sensitive and will question results due to bubbles, dust etc on the ID-MTS™ Cards.
- To prevent damage to the equipment or injury to the operator; access to all DOORS, DRAWERS or COVERS must be requested through the software
- Refer to SOP *Ortho Vision® Quality Control and Resources* for a full list of limitations

REFERENCES:

Micro Typing Systems Instructions for use
MTS Cards Instructions for Use
Ortho Vision Reference Guide

RELATED DOCUMENTS:

SOP *Ortho Vision® Result Management*
SOP *Ortho Vision® Quality Control and Resources*

APPENDIX: NA

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	