1.0 Purpose

This document provides guidelines for routine testing of samples on the ORTHO VISION® Analyzer. The ORTHO VISION® Analyzer is the primary method for testing.

1.1 Principle

The Vision analyzer will routinely query the Cerner Millennium LIS for any pending electronic physician ordered blood bank test for samples that have been identified on board by scanning their CM accession number barcode. Examples of bi-directionally interfaced blood bank tests are ABORh, Antibody Screen and Cord.

During computer downtime and for blood bank tests which are not resulted back to KPHC, manual test ordering must be done using the Vision console. Examples of non-interfaced tests are antibody panel identification, crossmatch IAT, and antigen typings for patients or donor units.

When donor units are inventoried into Cerner Millennium, a donor unit confirmation test is created and pending. However, Unit Confirmation is uni-directionally interfaced. The corresponding donor unit confirmation test must be ordered manually on the Vision analyzer for the associated donor unit barcode. System accepted unit confirmation results will automatically upload to CM.

1.2	**Test Profiles**

Test	Interfaced	MTS Gel Card
ABORh	Yes - bi-directional	A/B/D + Rev
ABSC	Yes - bi-directional	IgG
Crossmatch IAT	No	IgG
Panel A Auto	No	IgG
Panel A	No	IgG
Panel B Auto	No	IgG
Panel B	No	IgG
Panel C Auto	No	IgG
Panel C Ficin 37C	No	Buffer card
Panel C Ficin IAT	No	IgG
Cord	No	A/B/D + Rev and IgG
Rh Phenotype	No	D/C/E/c/e
O Pos Unit Type	Yes Uni-directional	Anti-A,B
Rh Pos Unit Type	Yes Uni-directional	A/B
Rh Neg Unit Type	Yes Uni-directional	A/B/D

2.0 Scope

	CLS trained and deemed competent for Ortho Vision operation.

3.0 Safety Precautions

a.	Use of PPE and current biological hazard safety practices will be followed as defined in the laboratory safety manual.
b.	If accessing the testing area, long hair should be pulled back to avoid being caught by internal moving components.
c.	Handle all equipment with care. Mechanical parts may have sharp edges, pinch points, and corners that potentially could cause injury.

4.0 Specimen

a. Whole blood pink top EDTA anticoagulated samples should be centrifuged at the appropriate calibrated RPM and time prior to testing on the analyzer.

b. Specimen types that are supported on the Vision

Sample Type	Liquid Type (on-screen selection)	Supported Testing
Whole Blood (pink EDTA anticoagulated centrifuged)	CENTBLOOD	Antigen, Antibody, Crossmatch
Donor segments	PACKEDCELLS	Unit ABO typing, Crossmatch, Antigen
Plasma only	PLASMA	Antibody, Crossmatch
3% red cell suspension	3CELLS	Antigen, Crossmatch
0.8% red cell suspension	0.8CELLS	Antigen, Crossmatch

c. Specimens which are grossly Hemolyzed, Icteric, or Lipemic should not be run on the analyzer. Error codes of CI (Contrast Interference) on the Antibody Screen will require testing to be performed on the manual bench.

d. Donor unit segments are prepared by using 1 segment emptied into a skinny 10mm X 75mm tube and labeled with ISBT barcode aliquot label (back of unit bag).
If alternate tubes must be used, make sure the minimum depth for sample volume is met.

Tube Diameter	Segments	Quantity (Height from sample bottom)
10 mm	1	6 mm
12 mm	2-3	6 mm

5.0 Equipment Calibration and Maintenance

a. Daily PM performed successfully prior to QC testing.

b. Weekly and Monthly PM when required are performed successfully prior to QC testing.

6.0 Supplies

Materials	Storage requirements	User 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
Sample Trays	2-25°C	Room temperature	
MTS® Diluent 2	2-8°C	Room temperature	Does not include EDTA. Use in dilution of non-red cell sample types. Diluents should not be left on the instrument longer than 24 hours.
MTS® Diluent 2 Plus	2-8°C	Room temperature	Contains EDTA. 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% SURGISCREEN® Reagent Red Blood Cells	2-8°C	Room temperature	
Ortho Panel A. B, C untreated, and Ficin treated panel cells (0.8%)	2-8°C	Room temperature	Follow IFU insert. Select heterozygous positive control cells for Rh Phenotype or Antigen typing as recommended.

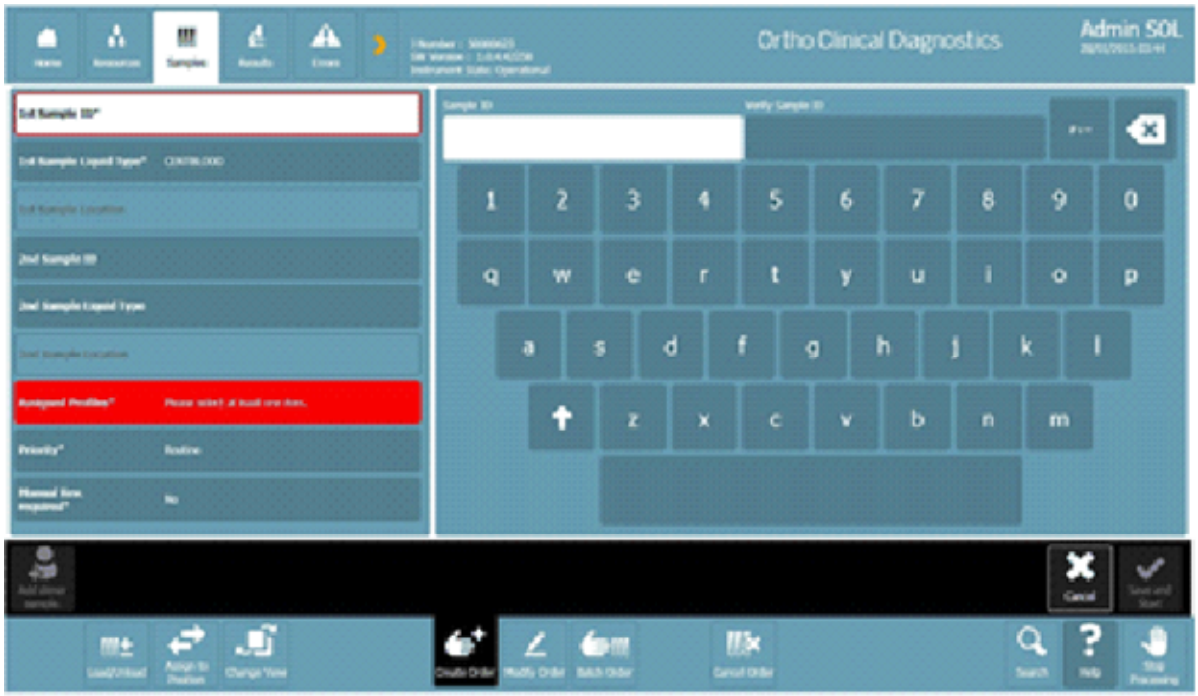
7.0 Quality Control

a.	Daily QC has been performed and verified as passed before performing patient testing.

b.	Non-routine QC must be performed as needed with patient testing and is verified as completed and passed each day of use.
c.	Refer to **Ortho Vision Quality Control** SOP for additional instructions.

8.0 Procedure

Step	Action
	NOTE: You can create an order for a sample not yet loaded on the VISION by touching **Create Order** and scanning/manually entering in the Sample ID.
a.	**Loading Samples** 1. Touch Samples tab > then select a ring position into which you want to load samples. 2. Touch Load/Unload and open the door. 3. Select any additional ring positions into which you want to load samples (you may select all six). 4. Place the rack or racks in the Load Station and close the door. Result: The system will perform an inventory and post the samples.
b.	**Creating an Order for a Single Sample Manually without the Bidirectional Interface.** **Ordering a Type and Screen** 1. Touch Samples tab > Touch the sample icon to select it. 2. Touch Create Order. 3. Fill in the required details: Sample ID (if sample was not selected on previous screen), profiles to be run, priority and manual review (not required). • Profiles will be listed to the right; selected tests will be highlighted in white. Select all test profiles to be run (e.g. ABORh and ABSC for a Type and Screen order). 4. To start processing, touch the Save and Start button.



For non-barcoded samples, manually type in twice for the double-blind sample ID entry or for barcoded samples, scan the tube with the hand-held barcode scanner. With this version of software, the scanner fills in both areas.
Select the profile(s) and any additional requirements.

Testing is initiated on samples when all test conditions and system requirements are met. Requirements are defined in the system Setup according to individual laboratory needs. An error code will be generated when test cannot be initiated due to missing requirements.

Step	Action
c.	**Creating a Batch Order** The purpose of the batch order option is to create an order with the same profile for multiple samples. To program a batch order: 1. Touch Samples tab > Touch Create Batch. 2. Touch Sample ID and scan the samples to be included or select the sample IDs from the list displayed on the screen. This list corresponds to all the sample IDs which are already on board. • **NOTE:** All the samples included in a **same batch order** must belong to the **same sample type**. 3. Fill in the required details: Profile to be run, Priority, and Manual Review (Not required). 4. To start processing, touch the Save and Start button.
d.	**Ordering Donor Unit Confirmation Test** 1. Touch Samples tab > Touch Load/Unload and load donor sample. 2. Touch sample icon > Touch Create Order/Create Batch. 3. Fill in the required details: Sample ID (if sample was not selected on previous screen), Profile to be run, Sample Type **(PACKEDCELLS)**, Priority, Manual Review (Not required). 4. Select appropriate unit type confirmation test Profile. **Unit Label Type** / **Unit Confirmation Profile** O Pos / O Pos Unit Type A/B Rh Pos / Rh Pos Unit Type A/B/O Rh Neg / Rh Neg Unit Type
e.	**Ordering a Crossmatch** 1. Touch Samples tab > Touch Load/Unload and load **recipient** sample. 2. Touch recipient sample icon > Touch Create Order. 3. Touch Assign Profile and select profile **Crossmatch IAT**. 4. Touch **Add Donor Sample**. • Touch Donor's Sample ID field and scan unit#. • Touch Sample Type and select **PACKEDCELLS** as sample type. 5. Repeat step 4 for additional units. **Note: The button "List" gives access to all sample IDs on board. The donor's sample ID can be selected from that list if the donor samples were preloaded.** 6. If **crossmatching part 1 and part 2** of the same unit#, **manually type** the unit# of part 2 with a hyphen e.g.**W117019255301-2**. **Repeat manual entry** of the **hyphenated unit#** in the **Verify Sample ID** field. 7. Change other order details if needed: Priority, and Manual Review (Not required). 8. Touch Save and Start. 9. Load donor samples.

Step	Action
f.	**Ordering an Antibody Panel** 1. Touch Samples tab > Touch Load/Unload and load patient sample. 2. Touch sample icon > Touch Create Order. 3. Touch Assign Profile and select Panel (A, B, or C profile type) 4. Touch Save and Start.
g.	**Ordering a Select Cell Panel** 1. Touch Samples tab > Touch Load/Unload and load patient sample. 2. Touch sample icon > Touch Create Order. 3. Touch Assign Profile and choose panel with selected cells to be tested. 4. Touch **Disable Assays**. 5. Touch Panel Cells that are **NOT** being tested (no longer white backlight). **NOTE:** Panel Cells that **are being tested** should be in **White**. 6. Touch Save and Start.
h.	**Ordering a Rh Phenotype** 1. Touch Samples tab > Touch Load/Unload and load patient/donor sample. 2. Touch sample icon > Touch Create Order. 3. Touch Assign Profile and select **Rh Phen**. 4. Touch Save and Start.
i.	**Ordering a Cord ABORh and DAT IgG** 1. Touch Samples tab > Touch Load/Unload and load patient sample. 2. Touch sample icon > Touch Create Order. 3. Touch Assign Profile and select **Cord**. 4. Touch Save and Start.

9.0 Limitations, Interpretation and Result Reporting

9.1	**Limitations**

a.	Unit confirmation testing is ordered for each unit inventoried through RECEIVE PRODUCTS in CM but is not interfaced with the Vision. Unit confirmation testing must be manual ordered on the Vision.
b.	Grossly hemolyzed, lipemic or icteric samples may lead to discrepant test results by VISION.
c.	Fibrin or particulate matter can interfere with gel card reaction.
d.	Mixed field reaction will be graded as MF by VISION.
e.	Very weak expression of the D antigen may not be detected.

f.	Discrepant results may occur due to aspiration of donor cells in a recently transfused patient sample. Donor cells are usually older, denser and heavier and will concentrate below the patient's own cells in a centrifuged sample.
g.	**Note:** CLS must troubleshoot and perform additional testing which may include manual methods to resolve discrepant results and questionable reactions.

9.2	**Interpretation of Results**

	Refer to **Ortho Vision Management of Results** SOP.

9.3	**Result Reporting**

	Refer to **Ortho Vision Management of Results** SOP. Ensure QC results are acceptable before reporting patient results.

10.0 Corrective Action

10.1	**QC Out of Acceptable Range**

a.	Patient results cannot be reported if QC does not meet acceptable criteria. QC that is run with patient testing must be repeated and successful before patient results can be reported.
b.	Investigate QC failure: review QC sample preparation, check reagents and gel cards for expiration date and for signs of contamination, and verify appropriate barcode labels.
c.	Refer to **Ortho Quality Control** SOP for additional instructions.

10.2	**Instrument Warning or Error Flag Displayed**

	Refer to **Ortho Vision Management of Results** SOP.

10.3	**Instrument Downtime Action Plan - Alternate Test Method**

	If the Vision is non-operational, the alternate method for Type & Screen is manual tube ABORh and manual Gel ABSC, for Cord DAT IgG is manual tube DAT IgG, for Crossmatch IAT and panel workup is manual Gel, for Unit Confirmation is manual tube.

11.0 Documents and Records

11.1	Patient test results are accessible for up to six months on board the Vision. Individual and batch reports can be accessed and printed as needed. Refer to **Ortho Vision Management of Results** SOP.

12.0 References

12.1	ORTHO Vision® Analyzer Quick Reference Guide, current revision.
12.2	ORTHO Vision® Analyzer ID-MTS® Gel Cards Reference Guide, current revision.
12.3	ORTHO Vision® Analyzer ID-MTS® Gel Cards Self-Service Customer Procedures Guide, current revision.