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Daily Maintenance and Quality Control, Ortho Vision™ Analyzer

Purpose

This document provides guidelines for performing daily maintenance and daily quality control for the Ortho Vision™ Analyzer.

Policy

- Daily maintenance is completed on the analyzer every 24 hours.
- Quality control testing will be performed each day of use for the reagents, cards, and diluents used in patient and/or blood product testing on the Ortho Vision™ Analyzer.
- The six (6) Quality Control test profiles must be determined acceptable prior to proceeding with all patient/product sample testing.
- The quality control results are determined acceptable prior to testing and reporting results.
- Unexpected results (qc failure) are investigated to determine the cause of the failure (e.g. improper test performance, faulty equipment, contamination or deterioration of reagents).
    - Patient/blood product testing performed between the QC failure and the most recent successful QC testing will be evaluated.
- All issues, problems and corrective actions taken must be documented on the *Quality Control and Maintenance Checklist-Ortho Vision™*
    - Issues such as error codes/failure codes, calls for vendor support, unusual maintenance activities (e.g. probe change), must be documented.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Materials

- Do not use reagents, cards, and QC samples beyond expiration date.
- Bring gel cards, reagents, and QC samples to room temperature prior to loading on the analyzer.
- Ensure that the exterior surface of the vials/bottles is completely dry.
- All reagents should be considered potentially infectious and should be handled as though they are capable of transmitting disease.

Ortho Reagents	Comments
Gel Cards Routine Use • MTS® A/B/D Monoclonal and Reverse Grouping • MTS® A/B/D Monoclonal • MTS® A/B Monoclonal • MTS® A,B Monoclonal • MTS® Monoclonal Control • MTS® Anti-IgG	• Store at 2-25°C. • Store in an upright position. • Use at room temperature. • Do not store cards for long term on analyzer.
Infrequent Use* (not to be routinely loaded on analyzer) • MTS® Monoclonal Rh Pheno* • MTS® Monoclonal Anti-C* • MTS® Monoclonal Anti-c* • MTS® Monoclonal Anti-E* • MTS® Monoclonal Anti-e*	• NOTE: Store at 2-8°C. • * The use of these cards and any other Antigen typing cards supplied by Ortho Clinical Diagnostics do not require daily QC. • Document the performance and acceptability of QC on *"Infrequent QC Form"* on day of use.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Materials Con't

Reagents • MTS® Diluent 2 Plus • MTS® Diluent	• Store at 2-25°C • Use at room temperature • Diluents should not be left on the analyzer longer than 24 hours.
Reagent red blood cells 10mL • 0.8% AFFIRMAGEN® (Reverse Grouping Cells) • 0.8% SELECTOGEN® (Antibody Screening Cells)	• Store at 2-8°C • Use at room temperature • Ensure reagent red cells are properly re-suspended prior to loading on analyzer. • Reagent red cells should not be left on the analyzer longer than 120 hours (5 days). • Once loaded the Reagent rbcs do not need to be removed from the analyzer until they expire (120 hours), as long as the analyzer is operational.
Reagent Panel Cells 3mL • 0.8% RESOVLVE® Panel A and Panel B	• Store at 2-8°C • Use at room temperature • Ensure reagent red cells are properly re-suspended prior to loading on analyzer. • Load and unload Reagent Panel Cells as needed. Do not routinely leave on analyzer.
Method Based Controls • AlbaQ-Chek®	• Store at 2-8°C • Use at room temperature • Once opened the controls can be used for 7 days.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure

Daily Tasks

Step	Action
1.	Prior to running QC samples perform Daily Tasks listed on the *Quality Control and Maintenance Checklist-Ortho Vision™* NOTE: Remove diluents from the analyzer before starting and place in refrigerated storage. Remove a refrigerated, non-expired set of diluents to warm up to room temperature. Refer to materials section above for on analyzer stability of reagents.
2.	From Home Screen touch "Show Health Check Report" to display current environmental conditions for the analyzer. • Document the ambient temperature displayed in the T1 row for today's date. Acceptable range is 21-27°C. • Document the warm (incubator) temperature displayed in the T2 row for today's date. Acceptable range is 35-39°C. Place a "S" (Satisfactory) if the displayed temperature is within acceptable range in the S/U row. Place an "U" (Unsatisfactory) if the displayed temperature is not within the acceptable range in the S/U row. If the temperature displayed is not acceptable, take the analyzer out of service and notify manager or designee.
3.	See separate procedures for instructions for completing Daily Maintenance (DM) Task and RS (Resources) Task. • Document DM Task is completed "P" (Passed) or "U" (Unsatisfactory) • Document RS Task is completed as "OK"
4.	In Daily Task Section initial in CLS Row for date all daily tasks are completed.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure Con't

Running a Quality Control (QC) Samples

Step	Action
1.	**Preparation of QC samples:** Weekly remove a new set of AlbaQ-Chek QC samples (1-4) and prepare DAT positive and negative samples: o Label a clean test tube with a "dat pos" barcode o Label a clean test tube with a "dat neg" barcode o Aliquot approximately half of an unused AlbaQ-Chek QC 2 sample, to the "dat pos" labeled test tube. o Add 2 drops of Anti-D reagent. Mix well. o Sample expires in 7 days o Aliquot approximately half of an unused AlbaQ-Chek QC 4 sample, to the "dat neg" labeled test tube. o Sample expires in 7 days Centrifuge AlbaQ-Chek QC samples (1-4) and the two dat control samples • The QC samples must be centrifuged prior to first use. o Subsequent upright refrigerated storage eliminates the requirement for further centrifugation unless mixing has occurred. • The samples must equilibrate to room temperature prior to loading on the analyzer. • Verify the samples are: o Not expired o Have been in use for 7 days or less
2.	To Load QC Samples • Touch Samples • Touch desired rack position • Touch Load/Unload • Follow directions on screen to open door and load sample rack containing QC samples. NOTE: Ensure that the QC sample barcodes are positioned correctly for the analyzer to read.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure Con't

Running a Quality Control (QC) Samples

Step	Action
3.	Touch the QC menu button (expand the menu bar to reveal the QC icon)  QC
4.	Each QC profile must be selected separately. Refer to Attachment A at the end of this procedure. **Profile # / Profile Name** 1 ABO/Rh 2 Antibody Screen 3 Cord Blood ABD 4 UC A B AB Pos 5 UC O Pos 6 DAT(IgG) Touch the Run QC Job button on bottom of screen.  Run QC Job
5.	Select the reagent and card lot numbers for QC Touch Save (checkmark in lower right corner).
6.	Repeat steps 4 and 5 for all profiles requiring QC.
7.	If QC testing result is indeterminate (?), it is acceptable to edit the column grade and accept the QC test as valid. Refer to Management of failed QC Results section below.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure Con't

Running a Quality Control (QC) Samples

Step	Action
8.	Review the QC testing and verify the following: **Appropriate QC Controls have been run** See table below. Verify the following on the Vision Screen: • QC has "Passed" for associated QC samples/Profiles • QC expiration date has updated to 24 hours in the future for all QC Profiles.
9.	Review all QC profile test results: Touch the Results menu button: • Touch the Search button • Scan in the QC sample barcode o Use the date range selection to view today's results (Alternately the gel card barcode (retrieved from the waste bin) can be scanned.) Verify each positive reactive result is graded as either 3+ or 4+ in reactivity. If any positive reactivity is 1+ or 2+ document on back of checklist (QC sample/Gel card), as it will be noted as a possible outlier or trend in QC.

QC Profile	QC Samples Run
1-ABO Rh	QC1 and QC3
2-AbScr	QC1 and QC3
3-Cord Blood ABD	QC1 and QC3
4 UC A B AB Pos	QC1 and QC3
5-UC O Pos	QC2 and QC4
6-DAT IgG	dat pos and dat neg

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Procedure Con't

10.	If any QC testing is not acceptable, go to section below-Management of failed QC Results.
11.	If all QC profiles have passed and been reviewed as described above document "S" on Quality Control and Maintenance Checklist-Ortho Vision™ form under Daily QC.

Registering a new lot of AlbaQ-Chek®	
Step	**Action**
1.	Touch the QC menu button  QC
2.	Select the profile you wish to process, and touch the Run QC Job action button.
3.	To update the QC sample lot: • Touch "Change OCD QC Sample ID" displayed on the left hand side of the touchscreen.
4.	Delete the existing Lot ID (sample ID) and use the handheld barcode scanner to scan in the new sample ID for each control vial. Touch Save.
5.	Repeat steps 2-4 for each MBC Profile.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure Con't

QC of different ID-MTS Gel Card lots or Reagent Red Cell Lots	
Step	**Action**
1.	Touch the QC menu button  QC
2.	Select the profile which needs updating, and touch the Run QC Job action button
3.	To update the reagent or card lot: • Touch "Reagent Lots" or "Card Lots" displayed on the left-hand side of the touchscreen. • If there is more than one reagent lot loaded on the instrument, the default selection is the lot that was most recently registered. Touch twice to view all lot numbers that are loaded on the analyzer.
4.	Select the desired lot for the profile and Touch Save.
5.	Repeat steps 2-4 for each additional lot of reagents or cards for which the profile needs to be updated.

Viewing QC Result Summary	
Step	**Action**
1.	Touch the QC menu button  QC
2.	Touch the profile, then touch "Show MBC Report" on the bottom of the touchscreen.
3.	Touch Print or Touch Save to save to external file.
4.	Touch "Show QC History" on the bottom of the touchscreen to view QC results if multiple qc runs need to be reviewed.

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure Con't

Management of failed QC Results

Step	Action
1.	One or more QC Profile(s) may not be acceptable. The QC status will not be updated to "passed" and patient/blood product testing cannot proceed.

IF	THEN
An indeterminate result (?) is resulted for a QC profile	Retrieve the card from the manual review rack and examine. The column grade reaction may be edited to a valid result and QC profile will updated to "passed"
The analyzer gives unexpected QC result resulting in QC failure (i.e. 3+ vs Neg)	• Visually inspect reagents, qc reagents and cards. Take corrective action if needed (i.e. replace reagents/cards) • Repeat QC profile testing-if acceptable patient/blood product testing can proceed
The analyzer fails any QC profile at repeat testing.	Patient/blood product testing cannot be run. Proceed to Step 2.

2.	In the case of a true QC failure an investigation is required. This includes the following: • Place an "Out of Service" sign on the analyzer • Document all messages, errors on the *Quality Control and Maintenance Checklist-Ortho Vision*™™ (Corrective action log on reverse side). ○ If the analyzer is shut down document the date and time of shut down on the checklist. • Notify TS manager or designee • File a Quality Improvement Monitoring (QIM) report for the event • Contact vendor • Assess patient testing that was performed since the last successful qc run

Daily Maintenance and Quality Control, Ortho Vision™ Analyzer, Continued

Procedure Con't

Review and Documentation of QC Results	
Step	**Action**
1.	Monthly (or more frequent) review and assessment of quality control data is performed by the laboratory director or designee.
2.	Print outs of qc data or electronic records of qc data are generated per local protocol which document the review and assessment of quality control data. • Any outliers, trends or omissions not previously addressed will be followed up and documented with a Quality Improvement Monitoring (QIM) Report
3.	Records of quality control review and assessment shall be maintained per current record retention requirements.

Infrequent QC for Antigen Typing Cards	
Step	**Action**
1.	Obtain QC Materials and label appropriately.
2.	Load QC samples as patient samples and program appropriate test.
3.	Review results for QC testing once completed either on the analyzer display screen or by viewing printed report from analyzer.
4.	Document QC testing performed on *"Infrequent QC Form"*

Controlled Documents

- Quality Control and Maintenance Checklist- Ortho Vision™

Uncontrolled Documents

- Ortho Vision Analyzer, Reference Guide Pub. No.: J40050ENNA
- 2016-09-30
- Ortho Vision Analyzer, General Operator Training Manual, Ortho Clinical Diagnostics, OP_EN_02_2015
- Fung, Mark K. Ed. Technical Manual, 18th Ed. AABB, 2014
- AABB Standards, current ed.
- CAP Requirements, checklist, current ed.

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Distribution All SCPMG Transfusion Services

Master Control History of Change:		
Change type: new, major, minor etc.	**Version #**	**Description of Change**
New	1	New
Minor	2	Modified DAT QC Sample preparation, AlbaQ-Chek Control Vial 2 to be used for "dat pos" qc and Vial 4 to be used for "dat neg" QC. Added step to create aliquot tube for QC 6 sample instead of labelling the backside of AlbaQ-Chek Control Vial. Updated Attachment A with above changes for DAT QC Sample preparation. Added section for review and documentation of qc. Edited for clarity and typographical errors.
Minor	3	Added policy to document issues, problems and corrective actions taken on the *Quality Control and Maintenance Checklist-Ortho Vision*. Fixed typos for QC Profile Table in step 4. Added steps to describe what items to review to determine if QC is acceptable. Corrected AlbaQ-Chek Control Vial numbers for DAT QC on Attachment A, removed X in QC4 column for IgG Card, added Diluent 2+ to ABC, AA/B, and A,B card cells.

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Attachment A: Ortho Vision™ QC Profiles

MTS Cards & Reagents Used	AlbaQ-Chek® CONTROL VIAL				Custom QC Sample	
	QC1 A Neg, Anti- B, Anti D (rr)	**QC2** O Pos C & E Ag Pos Anti-A and Anti-B (R1R1)	**QC3** B Pos Anti-A (R1r)	**QC4** A_2B Pos No allo antibodies	**QC5** "dat pos" CONTROL (AlbaQ 2Sample W/2 Drops Anti-D)	**QC 6 "dat neg" CONTROL (AlbaQ 4 sample)**
ABD/Rev Card (Dil 2+, Affirmagen cells)	X		X			
IgG Card Selectogen cells	X		X			
IgG Card (Diluent 2)					X	X
ABD Card (Diluent 2+)	X		X			
A/B card (Diluent 2+)	X		X			
A,B card (Diluent 2+)		X		X		
QC Profile Number and Name	1-ABO Rh 2-Antibody Screen 3-Cord Blood ABD 4-UC A B AB Pos	5-UC O pos	1-ABO Rh 2-Antibody Screen 3-Cord Blood ABD 4-UC A B AB Pos	5-UC O pos	6-DAT IgG	6-DAT IgG

Procedural Notes: The reagents in the cards and the diluents must have a positive and negative reaction. UC Rh Neg test profile does not have a QC Profile since the Cord Blood ABD profile uses the same cards and reagents. XM IAT does not have a QC Profile since the DAT IgG test profiles uses the IgG card and dil 2. MTS Monoclonal Control Card formulation is identical to the ABD/Rev card control well. IFU states 'may' be tested in parallel with appropriate MTS Monoclonal Blood Grouping Card.