Indiana University Health	**Original Creation Date:** 07/12/2017	**Publication Date:** 02/04/2025
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 02/04/2027
	Category: Lab Methodist, Lab Riley, Lab University	
	Education: Level 3	

Approval Signatures: Magdalena Czader (Physician) (02/04/2025)

Ortho Vision Daily QC

Reference # 26428

I. PURPOSE

To provide daily proof of potency and specificity for all Ortho Vision reagents and analyzer performance.

II. SCOPE

Quality control must be done on all routine testing reagents on day of use. This SOP applies to all team member trained on the Vision. Lab Assistants and Tech may load samples, load resources and start QC tasks only, while MLT and MLS will be trained for all tasks.

III. STATEMENTS/REQUIREMENTS

A. All Ortho Vision reagents will have quality control performed each day of use.

B. When opening a new vial of reagent, document the date opened and your initials on the bottle.

C. Reagents will not be routinely used past the manufacturer's expiration date.

D. Any reagent not meeting QC standards will not be used and management will investigate the occurrence. Place unacceptable reagent lot in quarantine refrigerator.

E. All cards and specimens should be at room temperature.

F. The QC reagents will be centrifuged before first use. QC reagents should be stored upright in the refrigerator to avoid mixing of reagents, requiring additional centrifugation.

G. Not all profiles have specific QC, because the reagents have been quality controlled as part of another test. Examples of these test profiles include, but are not limited to:

Method	ID-MTS Card
CORD	A/B/D monoclonal grouping and reverse card
Titer	IgG card
Crossmatch	IgG card
Newborn Profile	IgG card, A/B/D monoclonal grouping card
MTS DAT	IgG card

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

CAP: College of American Pathologists

QC: Quality Control

V. EQUIPMENT/RESOURCES

A. Ortho Vison Swift and Vision MAX
B. A/B/D Monoclonal Grouping Cards
C. Anti-IgG Cards
D. Anti-D (Weak D) Ortho Reagen
E. NaOH
F. 0.8% Affirmagen
G. 0.8% Surgiscreen (I, II, III)
H. MTS Diluent 2
I. MTS Diluent 2 Plus
J. Buffer Cards
K. A/B/D Reverse Cards
L. Ortho QC Material, Vials 1-4.

VI. PROCEDURE

A. Description of Daily QC for the VISION

1. Profiles tested on a daily basis are outlined in the table below using the Ortho QC Material

#	Profile	Assigned QC Vials	Expected Results
1	ABORH	Vial 3	A Pos
2	ABO3CELL	Vial 1 Vial 4	AB Pos, IAT Neg B Neg, ABS Pos (anti-D, I and II)
3	DONOR	Vial 3 Vial 4	A Pos B Neg
4	ABORH2	Vial 2 (O Pos)	O Pos
5	3CELL	Vial 2 anti-c Vial 1 Neg	ABS Pos, anti-c, II and III ABS Neg
6	Weak D	Surgiscreeen 3	D Neg
7	Weak D2	Surgicscreen 1	D Pos
8	QC Buffer Card	Vial 3	Group A

2. When these methods are tested, document completion of QC testing on Ortho VISION

Maintenance Record.

3. If no testing performed on the VISION, initial the applicable box on Ortho VISION Maintenance Record. Daily Quality Control Peer Review is not applicable (NA) when no testing is performed and the corresponding box on Ortho VISION Maintenance Record should indicate "NA."

B. QC Procedure

1. Confirm that all required cards are loaded. If necessary, load new cards. If a new lot of cards needs to be added, go to Procedure: Vision - Changing Reagent Lots on the VISION

2. Load QC vials. If loading a new lot of QC vials or any VISION reagent, go to Procedure: Vision - Changing Reagent Lots on the VISION .

3. Place vials into a sample rack.

    a. In Diagram View, select Samples.

    b. Choose and highlight a position and select Load / Unload.

    c. Open the Load Station door and place the sample rack in the lower rotor position.

    d. Close Load Station door.

4. Select QC menu. (Touch > to expand the menu).

5. Daily QC: All QC profiles must be selected separately. QC testing will not begin until the QC Vials are loaded onto the analyzer.

6. Select Main profiles to be **tested daily.**

    a. ABO3CELL

    b. ABO RH

    c. ABORH2

    d. DONOR

    e. Weak D

    f. Weak D2

    g. Buffer Card

    h. Select Other As Needed QC profiles when appropriate.

7. After choosing the profile, select Run QC job for each test.

8. Confirm correct reagent and card lot numbers for QC for each test, refer to grid in VI.A.

9. Touch “Save” for each test. As long as the QC sample is loaded, with the corresponding Ortho card, then the QC will start after save is touched.

10. When testing is complete, review results.
    a. If QC is valid, it will be accepted.
        i. One may need to manually review results (Procedure: Vision - Manually Reviewing or Printing Results) before the results are accepted and QC valid.
    b. If results are not acceptable, determine the cause, correct problems, and rerun QC (go to step C.5).
11. Initial on the Ortho VISION Maintenance Record when QC and maintenance testing is complete.

C. Complete the Daily Quality Control Peer Review
    1. Ask a peer tech to review the completeness of the Ortho VISION Maintenance Record form.
        a. If the document is complete, the tech should initial in the applicable box on Ortho VISION Maintenance Record .
        b. If the document is incomplete, the tech should not initial but hand the form back to the testing tech for correction. After correction, then repeat steps until acceptable.
        c. If a peer tech is not available to review form for completeness, then notify the next appropriate tech (next shift) to review the document.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition

AABB Standards, current edition

CAP Standards, current edition

IX. FORMS/APPENDICES

Ortho VISION Maintenance Record

X. APPROVAL BODY

None

Indiana University Health	**Original Creation Date:** 07/12/2017	**Publication Date:** 02/26/2025
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 02/26/2027
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	Education: Level 4	
Approval Signatures: Magdalena Czader (Physician) (02/26/2025)		

Procedure: Vision - Changing Reagent Lots on the VISION

Reference # 27459

I. PURPOSE

To provide instruction for changing reagent lots on the Vision analyzers.

II. SCOPE

This SOP addresses the steps for changing the reagent lots used on the Vision analyzers. This SOP applies to team members trained to operate the Vision.

III. STATEMENT/REQUIREMENTS

None

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

QC: Quality Control

V. EQUIPMENT/RESOURCES

Equipment:	**Reagents**
Vision Swift or Max	Applicable Vision Reagents and/or QC

VI. PROCEDURE

A. Changing QC Lots

1. Touch the QC Menu Button.
2. Select the profile to be processed then touch the "RUN QC JOB" action button at the bottom of the screen.
3. To configure the QC:
   a. Touch "Change" QC Sample ID (left hand column on the screen)
   b. Enter the lot number of the QC reagent into the Sample ID box by scanning the barcode on the tube, using the handheld barcode scanner or manually entering.
   c. The QC reagent manually entered or scanned must match the same QC reagent vial number as previously entered.

#	Profile	Assigned QC Tubes	Expected Results
1	ABORH	Vial 3	A Pos
2	ABO3CELL	Vial 1 Vial 4	AB Pos, IAT Neg B Neg, ABS Pos (anti-D, I and II)
3	DONOR	Vial 3 Vial 4	A Pos B Neg
4	ABORH2	Vial 2 (O Pos)	O Pos
5	3CELL	Vial 2 anti-c Vial 1 Neg	ABS Pos, anti-c, II and III ABS Neg
6	Weak D	Surgiscreeen 3	D Neg
7	Weak D2	Surgicscreen 1	D Pos
8	QC Buffer Card	Vial 3	Group A

Rh and Antigen Typing

#	Profile	Assigned QC Tubes	Expected Results
1	Rh Phenotype card	Vial 1 Vial 2 Vial 3	Vial 1 Pos, R1R2, D+C+c+E+e+ Vial 2, Neg, R1R1, D+C+c-E-e+ Vial 3, Neg, R2R2, D+C-c+E+e-
2	C card	Vial 1 Vial 3	Vial 1 Pos, R1R2, D+C+c+E+e+ Vial 3, Neg, R2R2, D+C-c+E+e-
3	E card	Vial 1 Vial 2	Vial 1 Pos, R1R2, D+C+c+E+e+ Vial 2, Neg, R1R1, D+C+c-E-e+
4	c card	Vial 1 Vial 2	Vial 1 Pos, R1R2, D+C+c+E+e+ Vial 2, Neg, R1R1, D+C+c-E-e+
5	Anti-K antisera	Based on Surgiscreen	Pos = K+k+ Neg = K-k+

d. If manually entering the lot number of the QC reagent into the Verify Sample ID box, one must enter it a second time

e. If using the barcode scanner, a second entry is not necessary.

4. Repeat steps A.1-3 for all QC profiles.

B. Changing Lot Numbers of ID-MTS Gel Cards and Reagent Red Cells

1. Load lots requiring QC.
2. Touch QC. Touch the applicable QC Profile (see BBV-105 Ortho Vision Daily QC).
3. Touch Run QC Job.
4. To configure the ID-MTS Gel Cards and Reagent Red Cells
    a. Touch a **card lot** for each of the required card type or **reagent lot** for each required reagent kit (left hand column of screen).
    b. If there is more than one required lot loaded on the instrument, the default selection is the lot that was most recently registered.
    c. Touch the **card lot or reagent lot** twice to view all the lots that are loaded on the analyzer.
    d. For Weak D Testing, a vial QC method is **not used**.
        i. Surgiscreen 3 and 1 are used for this testing.
        ii. Update of the weak D reagent lot number and verify the lot number of NaOH by scanning these or manually entering into the applicable area on the screen.
        iii. Surgiscreen must be manually changed in this screen for the Weak D testing.
    e. For Anti-K Testing, a vial QC method is **not used**.
        i. Surgiscreen K+k+ and K-k+ are used for this testing.
        ii. Update of the Anti-K reagent lot number and verify the lot number of NaOH by scanning these or manually entering into the applicable area on the screen.
        iii. Surgiscreen must be manually changed in this screen for the Anti-K testing.
5. Select Manual Rev. Required, and touch Yes.
6. Touch Save. The system processes the QC job that was requested.
7. Repeat steps B.1-6 to QC other lots that are loaded.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERTIONS

None

VIII. REFERENCES

Quidel Ortho, edition Vision Operator Manual

IX. FORMS/ APPENDICES

None

X. APPROVAL BODY

None

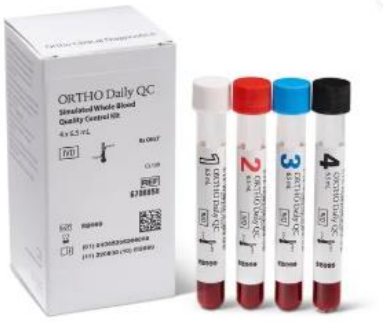
PROCEDURE #:

BBV 009

Whole Blood QC

All **4 tubes** used for QC.

Profiles in table and SOP.



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5	3CELL	Vial 2 anti-c Vial 1 Neg	ABS Pos, anti-c, II and III ABS Neg
6	Weak D	Surgiscreeen 3	D Neg
7	Weak D2	Surgicscreen 1	D Pos
8	QC Buffer Card	Vial 3	Group A

JKS 2.28.25

Payment Events	Status	Timestamps

docusign

Certificate Of Completion

Envelope Id: 47F4C57A-78D8-45ED-935B-735A5DD48C4E
Status: Completed
Subject: Complete with Docusign: vision qc.pdf, changing qc.pdf, Profile Card starting 2.28.25 JKS.docx
Source Envelope:
Document Pages: 8
Signatures: 0
Envelope Originator:
Certificate Pages: 1
Initials: 0
Jayanna Slayten
AutoNav: Enabled
950 N Meridian St
EnvelopeId Stamping: Disabled
Indianapolis, IN 46204
Time Zone: (UTC-05:00) Eastern Time (US & Canada)
jslayten@iuhealth.org
IP Address: 162.1.161.41

Record Tracking

Status: Original
2/28/2025 8:55:53 AM
Holder: Jayanna Slayten
jslayten@iuhealth.org
Location: DocuSign

Signer Events	Signature	Timestamp

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp
Jayanna Slayten jslayten@iuhealth.org Coordinator-Quality Reporting IU Health Security Level: Email, Account Authentication (None)	VIEWED Using IP Address: 162.1.159.41	Sent: 2/28/2025 9:05:43 AM Viewed: 2/28/2025 9:06:24 AM

Electronic Record and Signature Disclosure:
Not Offered via Docusign

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/28/2025 9:05:43 AM
Certified Delivered	Security Checked	2/28/2025 9:06:24 AM
Completed	Security Checked	2/28/2025 9:06:24 AM

Payment Events	Status	Timestamps