Indiana University Health

Indianapolis, IN 46202

Standard Operating Procedure Manual (SOP) – Transfusion Medicine

Form #:   BBQA-F017.00
Manual: Quality Assurance
Original Effective: 04/03/2017
Revised:................... NEW
Revision Effective: NEW

Supplier Notification Evaluation Form   Page 1 of 1

Supplier: _Quidce Ortho_   **Date Received:** _5/1/25_   **By:** _JKS_

Summary: _Delay in door openg on Vision Causig and inventory error_

Impact Assessment:
☐ Formal Recall   ☐ Inventory Shortage   ☒ Product Update
☐ Other (describe):

Immediate Action:
☐ Quarantine/Destroy/Return Inventory   ☒ Notify Staff   ☐ Notify Medical Director
☐ Notify Risk Management   ☐ Implement Temporary Procedure   ☐ None Needed
☒ Other (Describe): _MTS Trainig + Ackonwledgmet Sent 5/2/25_

Immediate Action Review: _gp 5/1/25_   _QA Coord /date_

Shift	Days _Manager_	Evenings	Nights _gp 5-1-25_
Supervisor Init/Date _gp 5/1/25_		_gp 5/1/25_	_gp 5/1/25_
Amin Dir Signature			Date _5/1/2025_
Medical Dir Signature			Date _5/1/25_

Long Term Action:
☐ Destroy/Return Inventory   Date: _____   ☒ None Needed
☐ Release Inventory   Date: _____
☐ Revise Procedure(s)   Date: _____   Change Control #s: _____
☐ Other (Describe):

Long Term Action Review:

Shift	Days	Evenings	Nights
Initials/Date			

	Signature		Date
Amin Dir			
Medical Dir			

QuidelOrtho

April 22, 2025

URGENT PRODUCT CORRECTION NOTIFICATION
Software Anomaly Preventing Inventory of Loaded Samples/Reagents Due to Loading Station Door Timing on the ORTHO VISION® and ORTHO VISION® Max Analyzers

Dear Valued Customer,

The purpose of this notification is to provide information regarding a software anomaly identified on the ORTHO VISION® and ORTHO VISION® Max analyzers, where the analyzer is unable to perform inventory of loaded samples and reagents if the loading station door is opened immediately after the allotted 20-second countdown in the 0.2 second window before the door re-locks.

Affected Product	Product Code (Unique Device Identifier)	Affected Software
ORTHO VISION® Analyzer for ID-MTS™ Gel Cards	**6904577** (10758750012817)	Version 5.16 and below
ORTHO VISION® Max Analyzer for ID-MTS™ Gel Cards	**6904576** (10758750007943)	Version 5.16 and below
ORTHO VISION® Analyzer for ID-MTS™ Gel Cards (Certified)	**6153434** (10758750035816)	Version 5.16 and below

Background
The loading station door unlocks for 20 seconds upon request to load samples or diluents. If the door is not opened within this period, it relocks <u>without</u> triggering a re-inventory since no user access occurred.

If the door is opened immediately after the allotted 20-second countdown ends but within the door's auto-relock timeframe, the user will be allowed to load samples, however, re-inventory will not be triggered as the software does not detect that the loading station door was opened. There are no error codes generated for this issue. An inventory event will take place the next time you properly access the loading station.

A complaint review was conducted over 11 years. This review produced 1 complaint that was confirmed for this issue and 3 other complaints which, although not confirmed, matched the signature for this issue.

Impact to Results

Failure to perform sample re-inventory may result in the mis-association of samples on the tray if new samples are loaded, removed or samples are moved to different locations, resulting in erroneous patient results. An erroneous immunohematology test may result in serious patient injury if not detected. The extent of patient impact would depend on the impacted test and the result.

QuidelOrtho does not recommend lookback of previous results because there is no way to detect erroneous results from this failure mode, as there is no associated error code. Please discuss any concerns with your laboratory Medical Director.

Resolution:

This software anomaly is currently expected to be resolved with software version 5.17.

REQUIRED ACTION

- When accessing the door to the loading station visually confirm that the timer has not reached the end of its 20 second window. If so, let the door lock reengage before accessing the load station through the user interface.
- If the loading door was opened at the '0:00' time, as timer expires, and no inventory is detected on the GUI, ensure a new loading event is initiated. To initiate a new loading event, open the loading station door, wait a few seconds and subsequently close it to facilitate an accurate inventory event.
- Complete and return the enclosed Confirmation of Receipt form no later than **April 30,2025**.
- Please forward this notification if the affected product was distributed outside of your facility

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Global Services Organization at 1-800-421-3311.

Enclosure: Confirmation of Receipt Form

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.

QuidelOrtho™

Confirmation of Receipt – Response Required

URGENT PRODUCT CORRECTION NOTIFICATION

Software Anomaly Preventing Inventory of Loaded Samples/Reagents Due to Loading Station Door Timing on the ORTHO VISION® and ORTHO VISION® Max Analyzers

*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:*   **30-APR-2025**

Send to: **Joe Falvo**   e-Mail Address: RA-OCDUS-CONFIRMAD@QUIDELORTHO.COM   Fax: 1.888.557.3759 or 1.585.453.4110

Verification Request

☐ *I confirm this contact information and no changes are required*

Please complete this section if any of this information has changed

IUH METHODIST HOSP	
Institution: UCN: 00045419	Institution:
Contact:	Contact:
Address: 1901 N SENATE AVE AG24	Address:
City: INDIANAPOLIS State/Prov: IN	City: State/Prov:
Zip/Postal Code: 46202 Phone:	Zip/Postal Code: Phone:
e-Mail: Fax:	e-Mail: Fax:

Please Confirm

I received the Urgent Product Correction Notification regarding a software anomaly identified on the ORTHO VISION® and ORTHO VISION® Max analyzers, where the analyzer is unable to perform inventory of loaded samples/reagents if the loading station door is opened immediately after the allotted 20-second countdown in the 0.2 second window before the door re-locks.

I understand that when accessing the door to the loading station I must visually confirm that the timer has not reached the end of its 20 second window. If so, I must let the door lock reengage before accessing the load station through the user interface.

I understand that if the loading door was opened at the '0:00' time, as timer expires, and no inventory is detected on the GUI, I must ensure a new loading event is initiated. To initiate a new loading event, I must open the loading station door, wait a few seconds and subsequently close it to facilitate an accurate inventory event.

Print Name: *Jaqpnne Slayten*

Phone Number: 317.948.9610   Date: 5/1/25

Signature: **Required**
Your signature confirms that you have received and understand this communication.

[signature]

Your Comments:

<u>If you are responding for more than one location</u>, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent: *Methodist Hospital / University Hospital / Orthy Hosp.*

For Customers Who Order from a Distributor | Distributor Name

If you order from a Distributor, please provide the name of your distributor

Content ID:

QuidelOrtho™

Confirmation of Receipt – Response Required

Communication ID: CL2025-113   Date of Issue: 22-APR-2025

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Verification Request

☐ *I confirm this contact information and no changes are required*

Please complete this section if any of this information has changed

Institution: IU HEALTH UNIVERSITY HOSPITAL	UCN: 01108073	Institution:	
Contact: CLARIAN LAB		Contact:	
Address: 550 UNIVERSITY BLVD		Address:	
City: INDIANAPOLIS	State/Prov: IN	City:	State/Prov:
Zip/Postal Code: 46202	Phone:	Zip/Postal Code:	Phone:
e-Mail:	Fax:	e-Mail:	Fax:

Please Confirm

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Print Name: Tayama Slaypen

Phone Number: 317-948-960 Date: 5/1/25

Signature: Required — Your signature confirms that you have received and understand this communication.

Signature: *Jacqueline Slay*

Your Comments:

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent: Methodist Hospital / University Hospital / Riley Hospital