QuidelOrtho™

URGENT

Month XX, 2024

URGENT FIELD SAFETY NOTICE

Potential For Aspiration From Unintended Sample Container During Sampling Center Processing on VITROS® 3600 Immunodiagnostic Systems and VITROS® 5600/XT 7600 Integrated Systems

Dear Valued Customer,

The purpose of this notification is to inform you that the VITROS® Systems listed below may experience an anomaly involving the Sampling Center, which may have been manufactured using a sub-optimal hardware part. You are receiving this notification because Ortho Clinical Diagnostics (QuidelOrtho™) has determined that your system may potentially be impacted. For a list of potentially impacted serial numbers, see Appendix 1: "Potentially Impacted Serial Numbers" found at the end of this notification.

Affected Systems	Product Code (Unique Device Identifier)
VITROS 3600 Immunodiagnostic System	6802783 (10758750002979)
VITROS 3600 Immunodiagnostic System (Refurbished)	6802914 (10758750007103)
VITROS 5600 Integrated System	6802413 (10758750002740)
VITROS 5600 Integrated System (Refurbished)	6802915 (10758750007110)
VITROS XT 7600 Integrated System	6844461 (10758750031610)

Summary

The Sampling Center identifies, manages, and analyzes patient samples. In addition, the Sampling Center is where patient samples are aspirated and dispensed for processing.

QuidelOrtho confirmed a complaint where the Sampling Center mechanism unintentionally disengaged from the UNIVERSAL SAMPLE TRAY (TRAY), resulting in the misalignment of the intended sample container to be aspirated. From our investigation of this single occurrence, QuidelOrtho determined that if this disengagement and misalignment occurs, it may cause multiple patient samples to be aspirated from an unintended sample container within the same TRAY and report the results using the incorrect patient samples. Based on our investigation, QuidelOrtho estimates the likelihood of this occurrence to be approximately 0.00000035% (Around 1 in 2.88 million tests.).

As can be seen in the table below, based on the average volumes of tests run annually, VITROS Integrated Systems may potentially see an occurrence of the anomaly once every 6-7 years.

Summary (Cont.)

VITROS System	Rate of Occurrence	Projected Time the Anomaly May Occur (In Years)
XT 7600	1 in 2,879,864	6.3
5600	1 in 2,879,864	7.1
3600	1 in 2,879,864	44.8

To create the situation which would allow the anomaly to potentially occur, the Sampling Center must have been manufactured with the sub-optimal part and TRAYS must be present at Metering Positions 1 and 4 simultaneously. (**See Questions and Answers for a diagram of the four Metering Positions.**) QuidelOrtho has included with this notification, a temporary TRAY loading procedure that ensures TRAYS are not at Metering Positions 1 and 4 simultaneously which, if adopted, will further reduce the risk of aspiration from an unintended sample container. Based on your laboratory's usage, this procedure has the potential to reduce the throughput of your VITROS System. Review your laboratory risk management plan(s) to assess the need for this further mitigation. Please note, this is an issue with part variability for some VITROS Systems, not all VITROS Systems will be affected (See Appendix 1).

Impact to Results

If this anomaly occurs, it is possible for the Sampling Center to aspirate sample fluid from an unintended sample container causing the assay result(s) generated from that unintended sample to be incorrectly associated with the intended sample. An erroneous result may lead to misdiagnosis and inappropriate physician decision resulting in patient harm. The degree of severity of patient harm depends on the magnitude and direction of the error, assay clinical utility, and patient condition. Acutely ill patients are most susceptible to misdiagnosis and sub-optimal management due to this failure mode.

A reduction in laboratory throughput may result in testing delays, which may be mitigated by devising a laboratory process that prioritizes STAT assays for acute and critically ill patients. (**See Questions and Answers for more details.)** Please note, this is an impact of the temporary TRAY loading procedure and not an impact of the anomaly itself.

A review of previously reported results is not recommended as the occurrence of the anomaly is not identifiable by the operator. The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms as well as the results of other tests. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

As of January 8, 2024, QuidelOrtho has received 1 complaint related to this issue and has received no reports of patient harm.

REQUIRED ACTIONS

- To reduce the risk of unintended sample aspiration, refer to the procedure provided in this notification titled, 'Temporary TRAY Loading Instructions'.
- QuidelOrtho recognizes that the 'Temporary TRAY Loading Instructions' procedure may not be tenable for all laboratories due to testing volumes. Review your laboratory risk management plan(s) to assess the need for this further mitigation.
- Acknowledge your understanding of this notification by completing the enclosed Confirmation of Receipt form no later than **Month DD, 2024**.
- Save this notification with your User Documentation or post this notification by each VITROS 3600/5600/XT 7600 System until this issue has been resolved.
- If you suspect that your laboratory has experienced the anomaly described in this notification and you have not already done so, please report the occurrence to your local Global Services Organization (formerly Ortho Care).

Resolution

QuidelOrtho has identified root cause however, our investigation is still ongoing. We are currently working on a Hardware Modification (MOD) to resolve this issue and will communicate again once the MOD or additional information is available. Current estimated availability date of the MOD is 2nd quarter 2024.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact our Global Services Organization at insert phone number.

Insert signatory if applicable in your region.

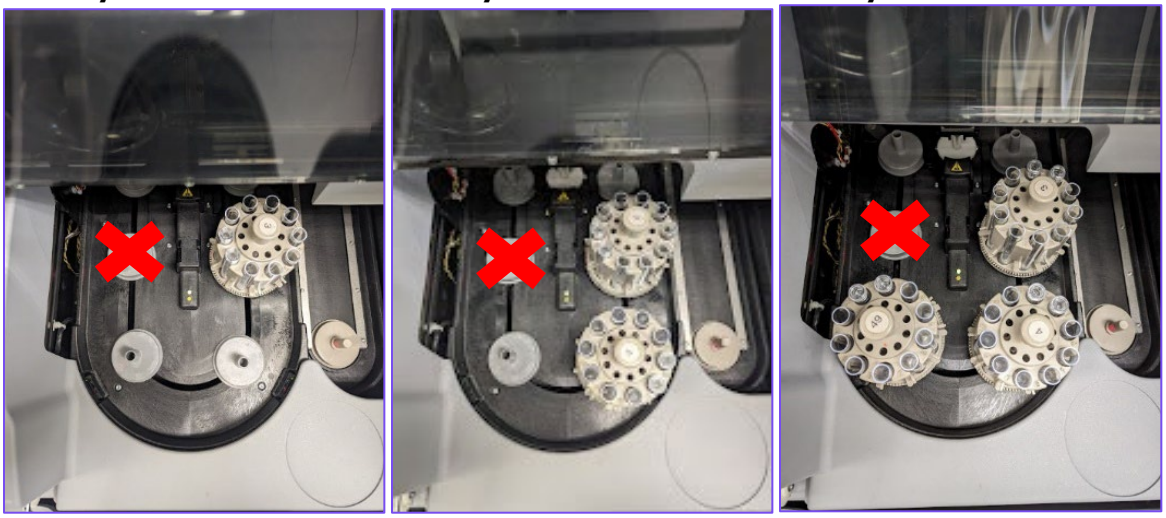
Enclosure: Confirmation of Receipt form (CL2024-014_EU_CofR)

Temporary TRAY Loading Instructions

To prevent an unintended sample from being aspirated *and* until the MOD that corrects this issue has been installed, QuidelOrtho recommends the following procedure:

1. Load a maximum of 3 TRAYS containing manually programmed or barcoded samples into adjacent Tray Transport positions, in the orientations shown below. The red ✖ in the images below designates the position where a TRAY should ***not*** be loaded.

1 Tray: **2 Trays:** **3 Trays:**



2. Touch the Start button  to begin sampling.

3. The TRAY(S) will be indexed into Metering Positions 1, 2, and 3. (See Questions and Answers for a diagram of the 4 Metering Positions.)

4. Sampling will begin. After sampling has completed, the TRAY(S) will remain in their Metering Positions until assay processing has finished and the Status Line displays **Assays completed** (If All Reprocessing is 'On').

Temporary TRAY Loading Instructions (Cont.)

5. After all assay processing has been completed, the TRAY(S) will be returned to the loading area. **NOTE:** This requires that no more TRAYS are loaded onto the VITROS System until the preceding 3 trays have been returned to the loading area (as shown below) and removed.

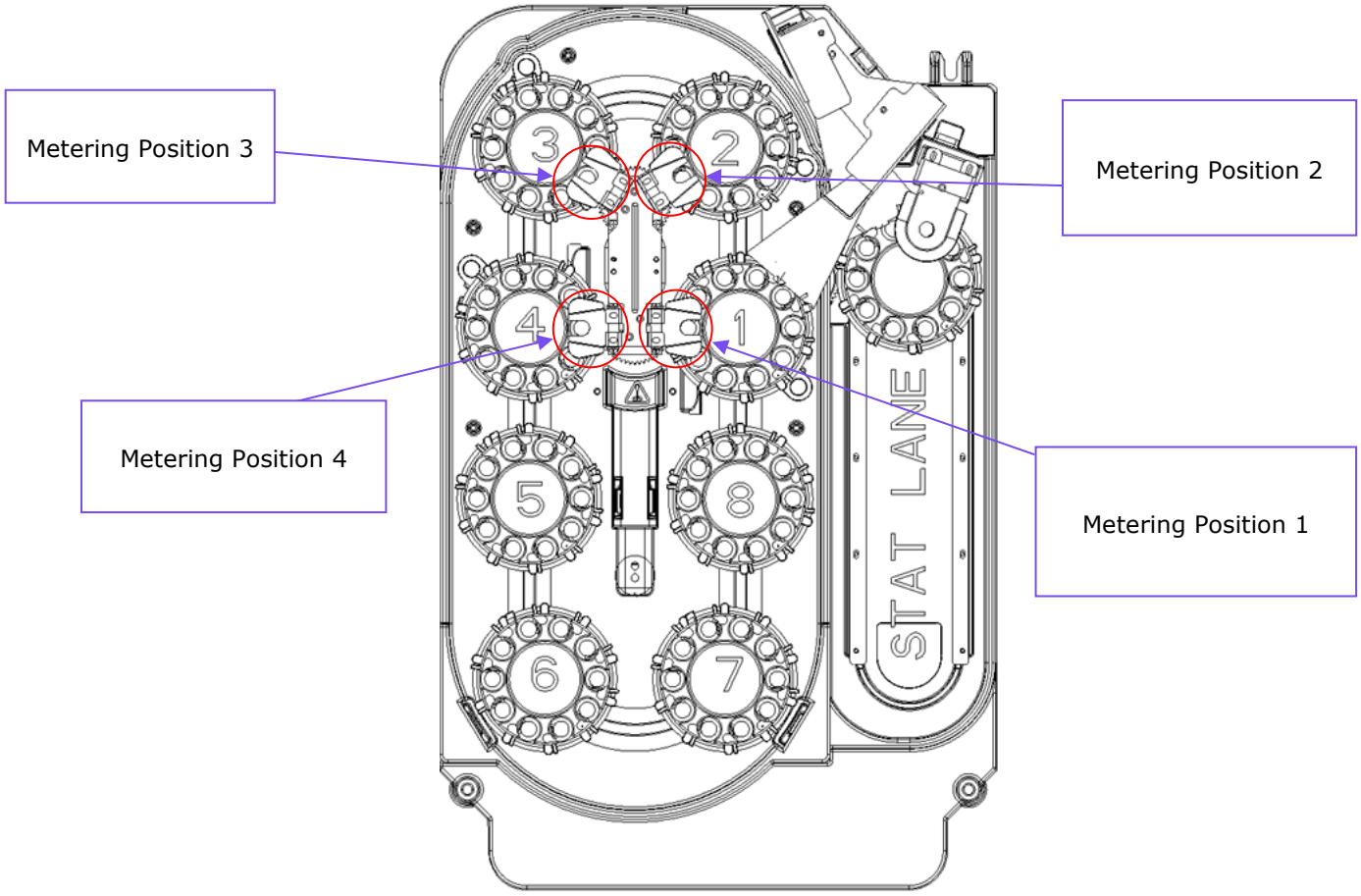
6. Repeat steps 1-5 as needed with up to only 3 TRAYS at a time.

Notes For Reprocessing:

- If 'All Reprocessing' is On, TRAYS will be held in the metering area until assay processing has finished and the Status Line displays **Assays completed.**
- If 'All Reprocessing' (Options -> Configure System -> Sample/Result Options) is turned Off, TRAYS will be returned to the loading area after sampling has completed *and* before assay processing has been completed.
- Turning 'All Reprocessing' Off may allow the VITROS System to increase throughput while performing this temporary loading procedure.
- Turning 'All Reprocessing' Off will disable Reflex Dilution and Routine Reprocessing. Unreported results will not be indicated in the reprocessing log and the LIS or the operator must manually handle all reprocessing.

Questions and Answers

1. **Where are the four Metering Positions located?**



2. **Is the STAT Lane affected by this anomaly?**

   No, QuidelOrtho has determined that the anomaly does *not* affect the STAT Lane. Refer to your VITROS System Reference Guide for instructions on proper usage of the STAT Lane.

3. **Are automation tracks affected by this anomaly?**

   No, samples metered via an external laboratory automation track are not affected. Only TRAYS loaded into the Sampling Center are susceptible to this anomaly.

4. **Are there Condition Codes associated with this anomaly?**

   No, QuidelOrtho's investigation has determined there are no specific indicators that the anomaly has occurred.

5. Are the VITROS XT 3400 and 4600 Chemistry Systems affected by the anomaly?

No, the VITROS XT 3400 and 4600 Systems are not affected due to differences in hardware design.

Appendix 1: Potentially Impacted Serial Numbers

VITROS System	Potentially Impacted Serial Numbers
VITROS 3600 Immunodiagnostic System	J36001164 through J36001692 (inclusive)
VITROS 5600 Integrated System	J56003170 through J56004741 (inclusive)
VITROS 5600 Integrated System*	J56000280, J56000330, J56000415, J56000631, J56000634, J56000721, J56000839, J56000871, J56001088, J56001209, J56001228, J56001265, J56001305, J56001355, J56001834, J56001855, J56001941, J56001998, J56002111, J56002239, J56002476, J56002492, J56002531, J56002561, J56002649, J56002655, J56002658, J56002691
VITROS XT 7600 Integrated System	J76000109 through J76001913 (inclusive)

***These specific VITROS 5600 Systems are impacted due to a service event involving the Sampling Center. Each number listed identifies an individual VITROS 5600 System.**

QuidelOrtho™

Confirmation of Receipt – Response Required

Communication ID: CL2024-014_EU Date of Issue: DD-MMM-2024

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

Send to: Name e-Mail Address: email address Fax: Fax Number

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____

Please Confirm

I received the Urgent Field Safety Notice regarding the anomaly involving the Sampling Center on VITROS 3600/5600/XT 7600 Systems.

I acknowledge my laboratory's understanding of the issue described in this notification.

My laboratory will follow the Required Actions listed in this notification.

Please choose from the following:

☐ My laboratory has decided to use the temporary TRAY loading procedure.
☐ My laboratory has decided not to use the temporary TRAY loading procedure.

Print Name: _____

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

Phone Number: _____ Date: _____

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:

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	

Content ID: _____