

August XX, 2023

URGENT FIELD SAFETY NOTICE

Out of Specification Proboscis/Piston Assembly for VITROS 5,1 FS/XT 3400/4600 Chemistry Systems, VITROS 3600 Immunodiagnostic Systems, VITROS 5600/XT 7600 Integrated Systems May Not Perform as Intended

Dear Valued Customer,

The purpose of this notification is to inform you of an issue affecting the Proboscis/Piston Assembly, which is a component used in various VITROS® Systems to aspirate and dispense reagent or sample fluids. Due to a manufacturing issue, some Proboscis/Piston Assemblies manufactured between 07-Apr-2022 and 19-Dec-2022 may not perform as intended.

| Impacted Systems | Product Code (Unique Device Identifier) | Part No. |
|--|--|----------|
| VITROS 5,1 FS Chemistry System | 6801375 (10758750001132) | J55375 |
| VITROS 5,1 Chemistry System (Refurbished) | 6801890 (10758750001644) | |
| VITROS 3600 Immunodiagnostic System | 6802783 (10758750002979) | |
| VITROS 3600 Immunodiagnostic System (Refurbished) | 6802914 (10758750007103) | |
| VITROS 4600 Chemistry System | 6802445 (10758750012343) | |
| VITROS 4600 Chemistry System (Refurbished) | 6900440 (10758750033201) | |
| VITROS 5600 Integrated System | 6802413 (10758750002740) | |
| VITROS 5600 Integrated System (Refurbished) | 6802915 (10758750007110) | |
| VITROS XT 3400 Chemistry System | 6844458 (10758750031986) | |
| VITROS XT 7600 Integrated System | 6844461 (10758750031610) | |

Summary

Ortho Clinical Diagnostics (QuidelOrtho™) received 12 complaints related to this issue as of 31-Jul-2023, we have received no complaints specifically for biased results related to this issue nor have we experienced biased results during our investigation.

QuidelOrtho confirmed the issue and determined that certain Proboscis/Piston Assembly (or Assemblies) manufactured between 07-Apr-2022 (Date code: 040722) and 19-Dec-2022 (Date code: 121922) may not perform as intended due to an out-of-specification barrel component. This may cause VITROS® VersaTips and/or VITROS® MicroTips to be improperly seated on the barrel component of the Assembly, which may result in an increased frequency of condition codes related to the actions of tip pickup, aspirate, dispense, mix, tip-seal, and discard. Due to the small VITROS MicroTip and VersaTip dimension variability (within manufacturing tolerances) and the way these Tips interact with the Assembly, Assemblies manufactured within the affected date range may not perform as intended based on the Tips currently in use.

To determine if your laboratory is using an Assembly that was manufactured within the affected date range, check the date code stamped into the barrel of the Assembly. Refer to the example image below to locate the date code on the barrel component of the Assembly.

If your laboratory has an Assembly with a date code between 040722 - 121922, the Assembly is considered affected and must be replaced.

QuidelOrtho will provide a credit OR no-cost replacement for each affected Assembly. **This includes all affected Assemblies in your laboratory including spare Assemblies not yet installed on your VITROS System.**



The condition codes related to this issue are:

| | | | | |
|----------------|----------------|----------------|----------------|----------------|
| TEL-49A | TMF-4GB | TM5-4DB | MF6-4LB | TMH-4FB |
| TMF-4GD | MFF-4ED | TEF-4AD | TE5-45G | TE5-45B |
| TML-49A | TMF-4EB | TEF-4AB | TMH-4DB | TEH-44B |
| PVD-015 | TM5-45G | MF9-72E | TE9-72E | TM9-72E |

See **Appendix 1** for a full description of each condition code.

Impact to Results

An affected Assembly may lead to a delay in generating results and/or failed calibration due to errors related to tip pickup, aspirate, dispense, mix, tip-seal, and discard.

There is a potential for falsely elevated results for the VITROS Gentamicin and Valproic Acid MicroTip Assays when a reagent under-delivery event has occurred. Falsely elevated results may lead to diagnostic confusion or misdiagnosis.

A review of previous results is not recommended due to the complexity of determining the frequency of condition codes in addition to determining which specific results were generated using an affected Assembly. However, the VITROS Systems impacted by this issue have built-in system functions to assist in detecting biased or incorrect results due to reduced sample volumes during sample/reagent metering:

- Pressure sensing to assist in the event of a poorly seated VITROS MicroTip or VersaTip.
- QuidelOrtho's proprietary Intellicheck® Technology, a series of technologies that perform, monitor, and verify diagnostic checks throughout sample processing, assay processing, and reporting results which may aid in detecting incorrect sample/reagent volumes.
- Performing the Leak/Hysteresis Test during daily maintenance may help detect this issue.

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 you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

REQUIRED ACTION

- Determine if any of the impacted VITROS Systems in your laboratory are using an affected Proboscis/Piston Assembly by checking the date code stamped into the barrel component. Once a replacement Proboscis/Piston Assembly is received, discard all affected Assemblies within the date range of 040722 - 121922.
- Determine if your inventory of VITROS spare parts contains any affected Proboscis/Piston Assemblies by checking the date code stamped into the barrel component. Once a replacement Proboscis/Piston Assembly is received, discard all affected Assemblies within the date range of 040722 - 121922.
- Ensure your laboratory is performing the Leak/Hysteresis test during daily maintenance and performing Quality Control to ensure a properly functioning Proboscis/Piston Assembly until a replacement Assembly is available.
- Complete the enclosed Confirmation of Receipt form no later than **August XX, 2023**. Upon receiving your completed Confirmation of Receipt form, QuidelOrtho will credit your account or send a replacement Proboscis/Piston Assembly (Part. No. J55375), if applicable.
- Post this notification by each VITROS 5,1 FS/3600/4600/5600/XT 3400/XT 7600 System until this issue is resolved.
- Please forward this notification if the affected product was distributed outside your facility.

Resolution

QuidelOrtho has determined the root cause and found that only Proboscis/Piston Assemblies manufactured between 040722 - 121922 are affected by this issue.

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 number**.

Insert signatory if required in you region.

Enclosure: Confirmation of Receipt Form

Appendix 1: VITROS System Condition Code Descriptions

| Condition Code | Description |
|----------------|---|
| TEL-49A | uS METERING Seal Tip 1?? Tip Seal - Seal failed |
| TMF-4GB | uIA METERING Get Tip MicroTip %s Pickup - Damaged tip |
| TM5-4DB | uIA METERING Aspirate CuveTip - Bubble |
| MF6-4LB | uWell Reagent Metering detected a bubble in uWell. |
| TMH-4FB | uIA METERING Mix Cuvette %s - bubble detected |
| TMF-4GD | uIA METERING Get Tip MicroTip %s Pickup - No tip |
| MFF-4ED | uW REAGENT METERING get tip at VTip pickup - No tip |
| TEF-4AD | uS METERING Get Tip at VTip Pickup - No tip |
| TE5-45G | uS METERING Aspirate ID:%s Routine - Underfill |
| TE5-45B | ID: %s, Pos %s, Bubble during uS Aspirate |
| TML-49A | uIA Metering CuveTip Seal Failure at 1° TIP SEALER |
| TMF-4EB | uIA METERING Get Tip VTip Pickup - Damaged tip |
| TEF-4AB | uS METERING Get Tip at VTip Pickup - Damaged tip |
| TMH-4DB | uIA METERING Mix CuveTip - bubble detected |
| TEH-44B | uS METERING Mix STAT Pos ID:%s - bubble detected |
| PVD-015 | Bubbles Detected. Inspect %s reagent in SUPPLY %d, Slot %d |
| TM5-45G | uIA METERING Aspirate ID:%s Routine - Underfill |
| MF9-72E | uW R METERING Leak Test failure - Min. press. change not seen |
| TE9-72E | uS METERING Leak Test failure; Min. pressure change not detected |
| TM9-72E | uIA METERING Leak Test failure; Min. pressure change not detected |

Questions and Answers

1. What if my laboratory recently discarded a Proboscis/Piston Assembly?

Unfortunately, without knowing the date code stamped into the barrel, QuidelOrtho cannot replace your inventory or credit your account. Only Assemblies currently in your laboratory's possession by the time this notification is received can be replaced or credited.

Confirmation of Receipt – Response Required

Communication ID: CL2023-176a_EU Date of Issue: DD-MMM-2023

URGENT FIELD SAFETY NOTICE

Out of Specification Proboscis/Piston Assembly for VITROS 5,1 FS/XT 3400/4600 Chemistry Systems, VITROS 3600 Immunodiagnostic Systems, VITROS 5600/XT 7600 Integrated Systems May Not Perform as Intended (Part Number J55375)

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

XX-AUG-2023

| | | |
|----------------------|------------------------------|--------------------|
| Send to: Name | e-Mail Address: Email | Fax: Number |
|----------------------|------------------------------|--------------------|

Verification Request

☐ I confirm this contact information and no changes are required

Please complete this section if any of this information has changed

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

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

Please Confirm

I received the Urgent Field Safety Notice regarding out-of-specification Proboscis/Piston Assemblies manufactured between 07-Apr-2022 and 19-Dec-2022 and will inspect the inventory of my Proboscis/Piston Assemblies.

Please choose from the following:

- ☐ My laboratory does not have any Proboscis/Piston Assemblies manufactured within the affected date range.
- ☐ My laboratory has only Proboscis/Piston Assemblies manufactured within the affected date range. I will discard the affected Assembly quantity listed below **after receipt** of my no-charge replacement(s).
- ☐ My laboratory has some Proboscis/Piston Assemblies manufactured within the affected date range and some manufactured outside the affected date range. I will discard all Proboscis/Piston Assemblies manufactured within the affected date range and indicate quantity to be **credited** below.

| Product Name / Part Number / Date Code Range | Date Code (MMDDYY) | Discarded Assembly Quantity |
|--|--------------------|-----------------------------|
| Proboscis-Piston Assembly / J55375 / 040722 - 121922 | | |
| Proboscis-Piston Assembly / J55375 / 040722 - 121922 | | |
| Proboscis-Piston Assembly / J55375 / 040722 - 121922 | | |
| Proboscis-Piston Assembly / J55375 / 040722 - 121922 | | |

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: _____