

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.