

January 30, 2026

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**Confirming Intended Reagent is Loaded During Manual Load Procedures**

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue that may occur on the VITROS™ Systems listed below when manually loading VITROS™ MicroSlide, MicroTip, and MicroWell reagents. This issue impacts all available versions of the VITROS™ System software.

<b>Systems Affected</b>	<b>Catalog Number</b> (Unique Device Identifier)
VITROS™ XT 3400 Chemistry System	684 4458 (10758750031986)
VITROS™ 3600 Immunodiagnostic System	680 2783 (10758750002979)
VITROS™ 3600 Immunodiagnostic System Refurbished	680 2914 (10758750007103)
VITROS™ 4600 Chemistry System	680 2445 (10758750012343)
VITROS™ 4600 Chemistry System - Refurbished	690 0440 (10758750033201)
VITROS™ 5600 Integrated System	680 2413 (10758750002740)
VITROS™ 5600 Integrated System - Refurbished	680 2915 (10758750007110)
VITROS™ XT 7600 Integrated System	684 4461 (10758750031610)
VITROS™ XT 7600 Integrated System - Certified	627 2222 (10758750035656)
VITROS® 5600 Integrated System (China)	690 4001 (10758750035786)
VITROS® XT 7600 Integrated System (China)	690 4003 (10758750035809)

**Summary**

QuidelOrtho received a customer complaint regarding an erroneous result generated using an unintended reagent cartridge for a different assay.

We investigated the complaint and determined that a combination of software anomaly and use error allowed the following sequence of events to occur:

### Summary (Cont.)

1. During a Manual Load procedure, a non-empty reagent cartridge was wrongly presented to the operator after opening the LOAD DOOR. (software anomaly)
2. After the LOAD DOOR was opened, the non-empty reagent cartridge, which should have been removed, remained in the slot, causing the VITROS System to identify it as the intended manually loaded reagent cartridge. (use error)
3. The unintended non-empty reagent cartridge was then used to process and report the erroneous result.

Our investigation confirmed that this issue can only occur *if the reagent presented at the load door is not removed and the intended reagent is not loaded* when performing the Manual Load procedure to load VITROS MicroSlide, MicroTip, and/or MicroWell reagents.

Until this issue is resolved in a future software update, to prevent this issue from occurring, customers are advised to do the following:

1. When performing the Manual Load procedure, **confirm that the intended reagent to be loaded matches what is entered** on the Manual Load Cart or Pack dialogue box.
2. During a Manual Load procedure, if a VITROS MicroSlide, MicroTip, or MicroWell reagent is presented after opening the LOAD DOOR, **that reagent must be unloaded, and the correct, intended reagent must be loaded into that slot.**

### Impact to Results

Using an unintended reagent cartridge for a patient test may produce an erroneous test result, which may or may not be clinically plausible. As test results are not predictable, an erroneous patient test result may lead to an inappropriate diagnosis and physician intervention. However, because this issue requires a unique combination of factors to occur, the probability of occurrence is considered improbable (extremely unlikely).

Due to the nature of the issue and the multiple steps that must occur to potentially produce an incorrect result, QuidelOrtho does not recommend a review of previous results. Discuss any concerns with your Laboratory Medical Director to determine the appropriate course of action. 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.

As of **29-Jan-2026**, QuidelOrtho has received 1 complaint related to this issue, with no reports of adverse effects.

### REQUIRED ACTIONS

- When performing the Manual Load procedure, confirm that the intended reagent to be loaded matches what is entered on the Manual Load Cart or Pack dialogue box.
- During a Manual Load procedure, if a VITROS MicroSlide, MicroTip, or MicroWell reagent is presented after opening the LOAD DOOR, that reagent must be unloaded, and the correct, intended reagent must be loaded into that slot.
- Complete the enclosed Confirmation of Receipt form no later than **06-Feb-2026**.

**REQUIRED ACTIONS (Cont.)**

- Save this notification with your User Documentation or post this notification by each VITROS 3600/4600/5600/XT 3400/XT 7600 System in your laboratory until the issue has been resolved.
- Please forward this notification if the affected system was distributed outside of your facility.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Technical Support team.

**Resolution**

The software anomaly contributing to this issue will be resolved in a future software update.

**Contact Information**

We apologize for the inconvenience this may cause your laboratory. If you have further questions, please contact our Technical Support team.



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Enclosure: Confirmation of Receipt form (CL2026-002dm\_CofR)

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