

Month DD, 2025

URGENT FIELD SAFETY NOTICE

VITROS® 4600 Chemistry Systems and VITROS® 5600 and XT 7600 Integrated Systems May Incorrectly Allow Use of VITROS® Diluent Packs Identified as Expired

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue that occurs when VITROS® Diluent Packs are manually loaded without entering a shelf expiration date on VITROS® 4600 Chemistry Systems and VITROS® 5600 and XT 7600 Integrated Systems.

Affected System Name	Catalog Number (Unique Device Identifier)	Affected SW Versions
VITROS® 4600 Chemistry System - Refurbished	690 0440 (10758750033201)	SW V3.2 to SW V3.8.3
VITROS® 4600 Chemistry System	680 2445 (10758750012343)	
VITROS® 5600 Integrated System - Refurbished	680 2915 (10758750007110)	
VITROS® 5600 Integrated System	680 2413 (10758750002740)	
VITROS® XT 7600 Integrated System – Certified	627 2222 (10758750035656)	
VITROS® XT 7600 Integrated System	684 4461 (10758750031610)	

Impacted Product Name	Catalog Number (Unique Device Identifier)	Impacted Lots
VITROS® Chemistry Products FS Diluent Pack 1 (Apo Diluent/UED)	680 1752 (10758750006984)	All Expired, Current, and Future Lots ¹
VITROS® Chemistry Products FS Diluent Pack 2 (BSA/Saline)	680 1753 (10758750006991)	
VITROS® Chemistry Products FS Diluent Pack 3 (Specialty Diluent/Water)	680 1754 (10758750007004)	
VITROS® Chemistry Products FS Diluent Pack 4 (DAT Diluent/DAT Diluent 2)	680 2326 (10758750002603)	
VITROS® Chemistry Products HbA1c Reagent Kit (contains Dil 5)	684 2905 (10758750030729)	

¹Until the software update which resolves this issue is available and installed.

Summary

The VITROS System software is designed to apply a "Reagent Expired" (RE) code to results if the 'Use Expired Reagents' option has been enabled, and an expired reagent is used. If 'Use Expired Reagents' has not been enabled, the VITROS System software is expected to report a "No Result" and apply an "Insufficient Inventory (II)" code when attempting to process samples using expired reagents, including diluents.

QuidelOrtho received a customer complaint stating that their VITROS® System had applied an RE code to results despite the 'Use Expired Reagents' option not enabled on their VITROS System.

We investigated the complaint and determined that a software anomaly exists in the VITROS System software, affecting all available versions. Despite the 'Use Expired Reagents' option *not* enabled, if a VITROS Diluent Pack Lot is manually loaded on VITROS 4600, 5600, and XT 7600 Systems with the shelf expiration date left blank, the VITROS System will flag the pack as expired but report results, applying an RE code to the results.

Please note that the anomaly will allow the VITROS System to report results using VITROS Diluent Packs which have not reached the shelf expiration date AND expired VITROS Diluent Packs (as printed on the product labeling), if the VITROS Diluent Pack was manually loaded with the shelf expiration date left blank.

In order for the anomaly to occur, the following must be true:

1. The 'Use Expired Reagents' option has not been enabled on the VITROS System.
2. The VITROS Diluent Pack to be used on the VITROS System is one of the products listed in the table above.
3. The VITROS Diluent Pack is manually loaded, **with no previous successful scans of the diluent pack barcode for that lot, on that specific VITROS System.**
4. The shelf expiration date for the manually loaded VITROS Diluent Pack Lot is not entered.

QuidelOrtho is working on a software update to resolve this issue. However, to prevent this issue from occurring in the interim, QuidelOrtho advises that the shelf expiration date must be entered when manually loading VITROS Diluent Packs on VITROS 4600, 5600, and XT 7600 Systems. Please refer to the "Manual MicroTip Pack Loading" procedure which can be found in V-Docs.

NOTE: Only the specific VITROS Diluent Packs listed above can produce the issue. Additionally, the VITROS Diluent Packs listed above are relied upon by certain VITROS® MicroTip and VITROS® MicroSlide assays to process samples. Assays affected will be dependent on the specific VITROS Diluent Pack(s) required during processing.

Impact to Results

When an RE code is applied to results, the time taken to troubleshoot and investigate the associated RE code may result in delayed patient results. Patient impact will depend on the impacted test.

If the onboard VITROS Diluent Pack has reached/exceeded the shelf expiration date, the results generated using the VITROS Diluent Pack may be incorrect. If not detected, the incorrect results may impact patient management with the extent dependent on the test, magnitude and direction of bias, and patient condition.

There is no risk of incorrect results if the onboard VITROS Diluent Pack has not exceeded the shelf expiration date.

This issue only impacts tests which require the use of VITROS Diluent Packs to generate results. Results from tests which do not require the use of VITROS Diluent Packs are unaffected by this issue.

Due to the nature of the issue and the multiple steps which must occur to potentially produce an incorrect result, QuidelOrtho recommends discussing any concerns regarding previously reported results 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 **22-MAY-2025**, QuidelOrtho has received 1 complaint related to this issue, with no reports of adverse effects.

REQUIRED ACTIONS

- To prevent this issue from occurring, the shelf expiration date must be entered when manually loading VITROS Diluent Packs on VITROS 4600/5600/XT 7600 Systems.
- View the **Reagent Management Supply 3** screen to check for any onboard VITROS Diluent Packs marked as expired.
 - For all VITROS Diluent Packs marked as expired, navigate to **View By Reagent → View Dil/ANC** and confirm the shelf expiration date matches the shelf expiration date on the product labeling.
 - If the shelf expiration dates do not match, discard the VITROS Diluent Pack and load a new VITROS Diluent Pack. QuidelOrtho will credit your discarded inventory. (Credit will only be issued for within-expiry products.)
- Complete and return the enclosed Confirmation of Receipt form no later than **Month DD, 2025**. Upon receipt of your completed Confirmation of Receipt form, QuidelOrtho will credit or replace your discarded inventory.
- Save this notification with your User Documentation or post this notification by each VITROS 4600/5600/XT 7600 System in your laboratory until the issue has been resolved.

REQUIRED ACTIONS (Cont.)

- Please forward this notification if the affected product 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 Global Services Organization.

Resolution

QuidelOrtho has determined root cause, and this issue will be resolved in an upcoming software update.

Contact Information

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

[Insert signatory if applicable]

Enclosure: Confirmation of Receipt Form (Ref. CL2025-111a_EU_CofR)

Questions and Answers

1. Where is the Reagent Expired (RE) code displayed?

The RE code is displayed on the Results Review screen, as well as on the lab report, and is also contained in the LIS upload data stream.

2. Where can I find the shelf expiration date?

The shelf expiration date can be found on the product carton and product label.

3. Can this issue occur with VITROS Diluent Packs which have reached the shelf expiration date?

Yes, this issue may occur with VITROS Diluent Packs which have reached the shelf expiration date, if they are manually loaded without entering a shelf expiration date.

4. Can this issue occur with other reagents?

No, this issue can only occur when manually loading the VITROS Diluent Packs listed above without entering a shelf expiration date.