

February 24, 2026

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Software Anomaly Causing VITROS™ Systems to Switch From VITROS™
Calibrator Kit 32 to VITROS™ Calibrator Kit 2 During ADD Load

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue involving the VITROS™ System software and VITROS™ Chemistry Products Assay Data Disk (ADD), Data Release Versions (DRVs) **6359** (released on 01-Jan-2026) to **6365** (released on 13-Feb-2026). This issue affects all available software versions.

Systems Affected	Catalog Number (Unique Device Identifier)	Affected ADD DRVs
VITROS™ XT 3400 Chemistry System	684 4458 (10758750031986)	6359 to 6365
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 customer complaints describing the inability to find VITROS™ Chemistry Products Calibrator Kit 32 in the Calibration Programming menu lot configuration while trying to calibrate VITROS™ Chemistry Products Na+, K+, Cl-, and ECO2 assays.

During the ADD loading procedure, after selecting 'All Assay Data', the Calibrator Kit dialog prompts the operator to select either:

- 'Use current kit' – to allow continued use of the calibrator kit configured (Can be either VITROS™ Chemistry Products Calibrator Kit 2 or VITROS Calibrator Kit 32).
- 'Change kit' – to switch the VITROS System calibrator configuration from VITROS Calibrator Kit 2 to VITROS Calibrator Kit 32 (or vice versa).

Summary (Cont.)

Our investigation into the complaints determined that customers using ADD DRVs **6359 - 6365** will experience a software anomaly where, selecting the 'Use current kit' option causes VITROS Systems previously configured to use VITROS Calibrator Kit 32 to unexpectedly switch to the VITROS Calibrator Kit 2 configuration during the ADD loading process.

*Please note: Our investigation has confirmed that the opposite does not occur if VITROS Calibrator Kit 2 was the configured kit prior to loading ADD DRVs **6359 - 6365**. Customers who utilize VITROS Calibrator Kit 2 are unaffected by this issue. Our investigation has also confirmed that VITROS™ 250/350 Chemistry Systems, which use the VITROS™ Chemistry Products Calibration Diskette, are not affected by this issue.*

This issue will be resolved in ADD DRV **6366** (available via e-Connectivity on 20-Feb-2026). Until your laboratory receives ADD DRV **6366**, when loading ADD DRVs **6359 - 6365**, VITROS Calibrator Kit 32 must be manually selected using the 'Change kit' option, to prevent the VITROS System from selecting VITROS Calibrator Kit 2 during the loading process. For instructions on how to load VITROS Calibrator Kit 32, see Appendix 1: Transition to VITROS Chemistry Products Calibrator Kit 32.

Impact to Results

This issue may temporarily disrupt the calibration process for VITROS Na+, K+, Cl-, and/or ECO2 assays, due to the additional time required to stop VITROS System operation, and perform the steps to reload the ADD and change the kit to VITROS Calibrator Kit 32. The additional time required to troubleshoot and reload the ADD is not expected to significantly impact patient testing or test turnaround time, as calibrations are typically performed during periods of low laboratory activity.

Current/Primary calibration data is not affected by this issue. Calibrations are also not deleted when this issue occurs and the ADD does not require reloading unless a new calibration for Na+, K+, Cl-, and/or ECO2 is required.

QuidelOrtho does not recommend a review of previous results, as there is no impact to patient results due to this issue. 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.

REQUIRED ACTIONS

- Until your laboratory receives ADD DRV **6366**, manually select VITROS Calibrator Kit 32 using the 'Change kit' option, when loading ADD DRVs **6359 - 6365**.
- Upon receipt, load ADD DRV **6366 (or above)** and manually select VITROS Calibrator Kit 32 using the 'Change kit' option.
- Complete the enclosed Confirmation of Receipt form no later than **10-MAR-2026**.
- Save this notification with your User Documentation or post this notification near your VITROS 4600/5600/XT 3400/XT 7600 System until the issue has been resolved.
- Please forward this notification if the affected product was distributed outside of your facility.
- If your laboratory has experienced the issue described in this notification and you

have not already done so, please report the occurrence to your local Technical Support team.

Resolution

This issue will be resolved beginning with ADD DRV **6366 (and above)**. After loading ADD DRV **6366 or above**, it is no longer required to manually select VITROS Calibrator Kit 32 in subsequently loaded ADD DRVs.

Contact Information

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



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Enclosure: Confirmation of Receipt form (Ref. CL2026-038dm_CofR)

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Appendix 1: Transition to VITROS Chemistry Products Calibrator Kit 32

For more information on transitioning to VITROS Chemistry Products Calibrator Kit 32, please refer to the product Instructions For Use.

To reload the current Assay Data Disk (ADD):

For e-Connectivity customers *only*: The ADD stays in the inbox of the VITROS System even

if the  icon is not displayed on the System Status screen, until a new ADD becomes available through e-Connectivity. During the ADD load process, select the 'Downloaded files' option at the 'Load System Information' dialog and then select 'Next'. Confirm the ADD to be loaded is the intended DRV. Do not load a DRV that is lower than what is currently loaded on your VITROS System.

Refer to the VITROS System user instructions as follows:

1. On the Load Method dialog, select the 'All Assay Data' option.
2. When prompted, select 'Change Kit' and then touch 'Next' and wait for the data to load. This may take a few minutes.
3. When prompted, select '32' to configure the VITROS System for VITROS Chemistry Products Calibrator Kit 32, then touch 'Next' and wait for the data to load.