QuidelOrtho™

URGENT

July DD, 2025

URGENT FIELD SAFETY NOTICE

VITROS® Chemistry Products Ca Slides, Generations 67 and Above, May Experience Increased Incidence of Calibration Failures

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue involving VITROS® Chemistry Products Ca Slides. Customers may experience an increased incidence of calibration failures when attempting to calibrate VITROS Ca Slides on VITROS® XT 3400 Chemistry Systems and VITROS® XT 7600 Integrated Systems.

Affected Product Name	**Catalog Number** (Unique Device Identifier)	**Affected GENs**
VITROS Chemistry Products Ca Slides	145 0261 (10758750009114)	67 and above
For *in vitro* diagnostic use only. VITROS Chemistry Products Ca Slides quantitatively measure calcium (Ca) concentration in serum, plasma, and urine using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).		

Impacted System Name	**Catalog Number** (Unique Device Identifier)
VITROS XT 3400 Chemistry System	684 4458 (10758750031986)
VITROS XT 7600 Integrated System	684 4461 (10758750031610)
VITROS XT 7600 Integrated System - Certified	627 2222 (10758750035656)

Summary

QuidelOrtho investigated complaints related to the inability to successfully calibrate VITROS Ca Slides on VITROS XT 3400 and VITROS XT 7600 Systems.

Our investigation determined that Generations (GENs) 67 and above of VITROS Ca Slides may experience an increased occurrence of Condition Code TH4-63J during calibration, on VITROS XT 3400 and VITROS XT 7600 Systems. Condition Code TH4-63J is generated when the REFLECTOMETER detects image variations which exceed an assay parameter defined on the Assay Data Disk (ADD). If Condition Code TH4-63J is generated during calibration, the calibration may fail.

Summary (Cont.)
To resolve this issue, QuidelOrtho has adjusted the assay parameter used by the REFLECTOMETER to process VITROS Ca Slides. This parameter adjustment will be implemented beginning in ADD DRV **6338** (and above). QuidelOrtho advises affected customers to load ADD DRV **6338** (or above) upon receipt.

Please note that if a successful calibration was performed, our investigation has confirmed there is no impact to the performance of VITROS Ca Slides.

Condition Code	Title	Definition
TH4-63J	REFLECTOMETER - Defect Detected/Slot: %s	The REFLECTOMETER detected an image variation that was outside limits.

Impact to Results
The issue described in this notification may cause a delay in obtaining patient results due to the additional time required to troubleshoot a failed calibration, impacting patient management to varying degrees depending on the duration of the delay and the clinical indication for the test. In the worst case, a delayed result may lead to delayed treatment, with the potential for patient harm.

QuidelOrtho does not recommend a review of previous results, as this issue does not impact patient results or quality control results. Discuss any concerns with your Laboratory Medical Director to determine the appropriate course of action.

As of **07-JUL-2025**, QuidelOrtho has received 125 complaints related to this issue, with no reports of adverse effects.

REQUIRED ACTIONS

- Upon receipt, load ADD DRV **6338** on your VITROS XT 3400 and/or VITROS XT 7600 System(s).
- Complete the enclosed Confirmation of Receipt form no later than **Month DD, 2025**.
- Save this notification with your User Documentation or post this notification by each VITROS XT 3400/VITROS XT 7600 System in your laboratory 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 with this product and you have not already done so, please report the occurrence to your local Global Services Organization.

Resolution
The issue resolves upon loading ADD DRV **6338** however, QuidelOrtho's investigation to determine root cause is still in progress.

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Contact Information
We apologize for the inconvenience this issue may have caused your laboratory. If you have further questions, please contact our Global Services Organization at insert phone number.

Insert signatory if applicable in your region.

Enclosure: *Confirmation of Receipt form (CL2025-178a_EU_CofR)*

Quidel Corporation (Quidel) and Ortho Clinical Diagnostics (Ortho), wholly owned subsidiaries of QuidelOrtho Corporation, are transitioning to our new logo and brand. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.

Questions and Answers

1. **How do I determine the GEN for VITROS Ca Slides?**