

July DD, 2025

URGENT FIELD SAFETY NOTICE

VITROS® Chemistry Products LAC Slides 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 an increased incidence of calibration failures when attempting to calibrate VITROS® LAC Slides on VITROS® XT 3400 Chemistry Systems and VITROS® XT 7600 Integrated Systems.

Affected Product Name	Catalog Number (Unique Device Identifier)	Affected Coatings
VITROS® Chemistry Products LAC Slides (300-Slide Format)	843 3880 (10758750004911)	0130 and above
VITROS® Chemistry Products LAC Slides (90-Slide Format)	815 0112 (10758750004454)	
For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products LAC Slides quantitatively measure lactate (LAC) concentration in plasma using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.		

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 ¹	627 2222 (10758750035656)

¹Availability will vary by region.

Summary

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

Our investigation determined that lots from Coating 0130 and above, of VITROS LAC Slides may be susceptible to an increased occurrence of Condition Code TH4-63J during calibration, on VITROS XT 3400 and 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 will fail.

Summary (Cont.)

To resolve this issue, QuidelOrtho has adjusted the assay parameter used by the REFLECTOMETER to process VITROS LAC Slides. This parameter adjustment will be implemented beginning in ADD DRV **6339** (and above). QuidelOrtho advises affected customers to load ADD DRV **6339** (or above) upon receipt. **ADD DRV 6339 will be available via e-Connectivity the week of August 4, 2025, and available via physical media the week of August 11, 2025.**

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

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

QuidelOrtho is actively assessing other VITROS® Chemistry Products MicroSlide assays which may require a parameter adjustment. Based on our assessment, the parameters for these assays may be adjusted in a future ADD release.

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 **28-JUL-2025**, QuidelOrtho has received 98 complaints related to this issue, with no reports of adverse effects.

REQUIRED ACTIONS

- Upon receipt, load ADD DRV **6339** (or above) 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 **6339** (or above) however, QuidelOrtho's investigation to determine root cause is still in progress.

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.

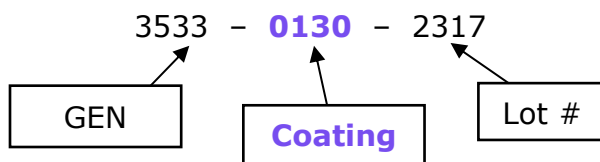
Enclosure: Confirmation of Receipt form (Ref. CL2025-201a_EU_CofR)

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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 Coating for VITROS LAC Slides?



2. When will ADD DRV 6339 become available?

ADD format	Availability Date
e-Connectivity	Week of 04-Aug-2025
Physical media	Week of 11-Aug-2025

Confirmation of Receipt – Response Required

Communication

ID: CL2025-201a_EU

Date of

Issue: DD-MMM-2025

URGENT FIELD SAFETY NOTICE

VITROS® Chemistry Products LAC Slides May Experience Increased Incidence of Calibration Failures (Catalog Numbers: 843 3880, 815 0112)

Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than: **DD-MMM-YYYY**

Send to: **Name**

e-Mail Address: **e-Mail address**

Fax: **Fax Number**

Verification Request

☐ I confirm this contact information, and no changes are required.

Institution: _____ UCN: _____

Contact: _____

Address: _____

City: _____ State/Prov: _____

Zip/Postal Code: _____ Phone: _____

e-Mail: _____ Fax: _____

Institution: _____

Contact: _____

Address: _____

City: _____ State/Prov: _____

Zip/Postal Code: _____ Phone: _____

e-Mail: _____ Fax: _____

Please Confirm

I received the Urgent Field Safety Notice regarding the potential to experience an increased incidence of calibration failures when attempting to calibrate lots from Coatings 0130 and above of VITROS LAC Slides on VITROS® XT 3400 Chemistry Systems and VITROS® XT 7600 Integrated Systems.

I understand that, upon receipt, I must load ADD DRV **6339** (or above) on my VITROS XT 3400 and/or VITROS XT 7600 System(s) to resolve this issue.

Please choose from the following:

- ☐ My laboratory does not use VITROS LAC Slides and therefore is not affected by this issue.
- ☐ My laboratory uses VITROS LAC Slides, I will load ADD DRV **6339** (or above) upon receipt.

Signature

Required:

Your signature confirms that you have received and understand this communication.

Print Name:

Phone Number:

Date:

Your Comments:

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations You Represent:

For Customers Who Order from a Distributor

Distributor Name

Content ID: