

February 27, 2026

IMPORTANT PRODUCT CORRECTION NOTIFICATION
VITROS™ Chemistry Products Mg Slides May Not Meet On-Analyzer Stability Specification

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue involving VITROS™ Chemistry Products Mg Slides, which may not meet the On-analyzer stability specification of ≤ 2 weeks.

Affected Product	Catalog Number (Unique Device Identifier)	Configuration	Affected Lots
VITROS Chemistry Products Mg Slides	825 5093 (10758750004621)	60-Slide Cartridges	All in-date and future lots.
	192 1204 (10758750000265)	18-Slide* Cartridges	
For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Mg Slides quantitatively measure magnesium (Mg) 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.			

*Not available in all regions.

Summary

QuidelOrtho became aware of the issue through customer complaints. The VITROS Mg Slides Instructions For Use (IFU) states an On-analyzer stability of ≤ 2 weeks, when the VITROS System is turned on; however, our investigation has determined that VITROS Mg Slides results may experience a negative drift outside acceptable limits (greater than 2 within-lab Standard Deviations (WLSD)) sooner than 2 weeks, when cartridges are stored on the VITROS System. This issue affects all current in-date and future lots of VITROS Mg Slides.

Until this issue is resolved, QuidelOrtho advises the following:

- Consider loading one cartridge of VITROS Mg Slides on your VITROS System at a time.
- Perform Quality Control (QC) testing daily as is stated in the Quality Control section of the VITROS Mg Slides IFU.
- If QC results are outside of established ranges, discard the cartridge, load a fresh cartridge of VITROS Mg Slides and repeat QC testing.
- If your laboratory frequently discards partially used 60-Slide cartridges, consider switching to the 18-Slide cartridges of VITROS Mg Slides at your next order date, if available in your region.

Impact to Results

This issue may cause a delay in reporting patient results due to the time taken to troubleshoot a failed QC result. However, the risk of serious patient harm is unlikely, as an estimated 2-hour delay would not impact patient management.

Impact to Results (Cont.)

QuidelOrtho does not recommend a review of previous results. As this issue can be detected by performing QC, there is no risk of erroneous patient results provided QC results are within acceptable ranges.

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 23-Feb-2026, QuidelOrtho has received 34 complaints related to this issue, with no reports of adverse events.

REQUIRED ACTIONS

- Consider loading one cartridge of VITROS Mg Slides on your VITROS System at a time.
- Perform QC testing daily. If results are outside of established ranges, discard the cartridge, load a fresh cartridge of VITROS Mg Slides, and repeat QC testing.
- Consider switching to the 18-Slide cartridges of VITROS Mg Slides, if available in your region.
- If multiple VITROS Mg Slides cartridges are loaded on the VITROS System, daily QC testing must be performed for each cartridge prior to use.
- Complete the enclosed Confirmation of Receipt form no later than **13-Mar-2026**.
- Complete the enclosed Request for Credit form to receive credit for discarded partially used cartridges of VITROS Mg Slides.
- Save this notification with your User Documentation or post this notification near each VITROS System in your laboratory until the issue has been resolved.
- Please forward this notification if the affected product was distributed outside your facility.
- If your laboratory has experienced this issue described in this notification and you have not already done so, please report the occurrence to your local Technical Support team.

Resolution

QuidelOrtho is still investigating to determine root cause. We will communicate again after root cause has been determined and this issue has been resolved.

Contact Information

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



Tan Keng Hao
Senior Lab Specialist CL and TM

Enclosures:

1. Confirmation of Receipt form (Ref. CL2026-035dm_CofR)
2. Request for Credit form (Ref. CL2026-035dm_CreditRequest)

Questions and Answers

1. What can I do to minimize the impact of this issue on my Mg results?

To help minimize the impact of this issue on your Mg results, please consider the following:

- Consider loading one cartridge of VITROS Mg Slides on your VITROS System at a time.
- Consider switching to the 18-Slide cartridges of VITROS Mg Slides if your laboratory frequently discards partially used 60-Slide cartridges.

2. Will performing daily QC detect this issue?

Yes, performing daily QC will detect if results have drifted outside 2 WLSD.

3. How often should I replace VITROS Mg Slides cartridges on my VITROS System?

A within-cart negative drift of greater than 2 Standard Deviations (SD) may be observed sooner than 2 weeks, when cartridges are stored on the VITROS System. Whenever QC is performed, if results are outside your acceptable limits, discard the cartridge, load a fresh cartridge, and perform QC again.

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