QuidelOrtho™

Important

Month DD, 2025

IMPORTANT PRODUCT CORRECTION NOTIFICATION
VITROS® Chemistry Products Performance Verifiers Do Not Meet 7-Day Reconstituted Stability for Cholinesterase

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ confirmed an issue involving VITROS® Chemistry Products Performance Verifiers I and II, which may not meet the 7-day reconstituted stability for Cholinesterase (CHE).

Affected Product	**Catalog Number** (Unique Device Identifier)	**Affected Lots**
VITROS Chemistry Products Performance Verifier I	806 7324 (10758750004317)	All Current and Future Lots
VITROS Chemistry Products Performance Verifier II	823 1474 (10758750004577)	

Impacted Product	**Catalog Number** (Unique Device Identifier)	**Format**	**Affected Lots**
VITROS Chemistry Products CHE Slides	191 4605 (10758750000241)	300 Slides	All within expiry lots
	800 4707 (10758750004225)	90 Slides	All within expiry lots

Summary

QuidelOrtho received complaints indicating that quality control (QC) results were reporting below the Range of Means listed on the Performance Verifier Assay Sheets when using VITROS Performance Verifiers I and II to monitor the performance of VITROS CHE Slides.

We investigated the issue and determined that VITROS Performance Verifiers I and II, when stored at 2-8°C, will maintain reconstituted stability up to 48 hours but may not maintain reconstituted stability up to 7 days for CHE, as specified in the Performance Verifier Assay Sheets.

Our investigation determined that up to 48 hours post-reconstitution, QC results were within 2x Within-lab Standard Deviation (WLSD). Beyond 48 hours, we determined that VITROS Performance Verifiers I and II may drift below 2x WLSD limits.

QuidelOrtho advises that customers may continue to use VITROS Performance Verifiers I and II to process QC of VITROS CHE Slides, monitoring QC results to detect a drift in performance below 2x WLSD limits. If a drift below 2x WLSD limits is detected, customers are advised to perform QC again using freshly reconstituted vials of VITROS Performance Verifiers I and II.

Summary (Cont.)
When performing QC to verify a new calibration of VITROS CHE Slides, freshly reconstituted vials of VITROS Performance Verifiers should be used, as aged VITROS Performance Verifiers may not detect a sub-optimal calibration.

QuidelOrtho has not seen evidence that suggests other assays supported by VITROS Performance Verifiers are affected by this issue. VITROS Performance Verifiers may be used to perform Quality Control according to the stability guidelines listed in the Assay Sheet for all other supported VITROS assays.

Impact to Results
The drift in VITROS Performance Verifiers I and II results below established ranges may cause QC failure, resulting in delayed patient results.

In certain scenarios, the drift in QC results may lead to the acceptance of a sub-optimal calibration, resulting in biased patient results. The maximum observed bias (simulated) can be seen below:

Impacted Product	Maximum Observed Bias (Within the Reference Range)
VITROS CHE Slides	+0.68 U/mL

QuidelOrtho does not recommend a review of previous results due to the low likelihood of biased patient results.

Discuss 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 **09-JUN-2025**, QuidelOrtho has received 12 complaints related to this issue, with no reports of adverse effects.

REQUIRED ACTIONS

- Monitor VITROS CHE Slides QC results to detect a drift in VITROS Performance Verifiers I and II below 2x Within-lab SD limits. If QC results are below 2x WLSD, perform QC again using freshly reconstituted vials of VITROS Performance Verifiers I and II.
- Complete the enclosed Confirmation of Receipt form no later than **Month DD, 2025**.
- Save this notification with your User Documentation or post this notification near your laboratory's fluid reconstitution location until the issue has been resolved.
- Please forward this notification if the affected products were 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 Global Services Organization.

Resolution
QuidelOrtho's investigation is ongoing, and we are working to identify root cause. We will communicate again after root cause has been determined and the issue has been resolved. Please note that until this issue is resolved, future lots of VITROS Performance Verifiers I and II may not meet the 7-day reconstituted stability for CHE.

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

Insert signatory if applicable in your region.

Enclosure: *Confirmation of Receipt form (Ref. CL2025-099a_CofR)*

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Questions and Answers

1. **Are previous lots of VITROS Performance Verifiers I and II affected by this issue?**

   No, QuidelOrtho has seen no evidence that previous lots of VITROS Performance Verifiers I and II are affected by this issue. If quality control results were within range, results should be accurate.

2. **Which lots of VITROS Performance Verifiers are currently available?**

VITROS Performance Verifiers Lot (I or II)	Expiry
V1665 (I)	14-Aug-2025
W1667 (II)	14-Aug-2025
X1901 (II)	20-Nov-2025
Y2110 (I)	25-Mar-2026
B2245 (I)	25-Mar-2026
A2114 (II)	25-Mar-2026
D2338 (II)	03-Jun-2026
E2828 (I)	03-Feb-2027
F2830 (II)	03-Feb-2027

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.