QuidelOrtho™

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Month XX, 2024

URGENT FIELD SAFETY NOTICE

Incorrect Diluent Lot Assembled into Sales Units of VITROS® Chemistry Products Performance Verifier Lots Q1174 and R1176

Dear Valued Customer,

The purpose of this notification is to inform you of an issue involving VITROS Chemistry Products Performance Verifier, Lots Q1174 (PVI) and R1176 (PVII).

Product Name	Product Code (Unique Device Identifier)	Affected Lots	Expiry
VITROS Chemistry Products Performance Verifier I and II	806 7324 (I) (10758750004317)	Q1174	01-Feb-2025
	823 1474 (II) (10758750004577)	R1176	01-Feb-2025
For in vitro diagnostic use only. VITROS Chemistry Products Performance Verifier is an assayed control used to monitor performance on VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.			

Summary
Ortho Clinical Diagnostics (QuidelOrtho™) received complaints regarding mis-matched diluent lots assembled into VITROS Performance Verifier, Lots Q1174 and R1176. QuidelOrtho investigated the issue and confirmed that some sales units of VITROS Performance Verifier, Lots Q1174 and R1176 contained the correct lyophilate but incorrect diluent. As can be seen in the table below, for product Lot Q1174, diluent Lot M9815 was found in some sales units instead of the expected diluent Lot Q1175. For product Lot R1176, diluent Lot P9967 was found in some sales units instead of the expected diluent Lot R1177.

Product	Product Lot	Diluent Lot Expected in Sales Unit (Correct)	Diluent Lot Found in Somes Sales Units (Incorrect)
PVI	Q1174	Q1175	M9815
PVII	R1176	R1177	P9967

The Instructions For Use (IFU) states: "Each bottle of lyophilate has a corresponding diluent labeled by number. Use the appropriate diluent in the reconstitution of the lyophilate." To ensure the appropriate diluent is being used, inspect your inventory of VITROS Performance Verifier, Lots Q1174 and R1176 and confirm the correct diluent was assembled into each sales unit. Sales units containing diluent Lots M9815 or P9967 *cannot* be used with product Lots Q1174 or R1176. Any sales units found containing diluent Lots M9815 or P9967 must be rendered unusable and discarded. QuidelOrtho will provide credit or replacement for all discarded sales units of VITROS Performance Verifier, Lots Q1174 and R1176.

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Impact to Results
The assays potentially impacted by this issue are VITROS Chemistry Products ECO_2 and Na^+ Slides, as the final concentration of each analyte comes partially from the diluent and partially from the lyophilate.

QuidelOrtho's investigation has determined that:

- VITROS Performance Verifier I (PVI), Lot Q1174 incorrectly reconstituted with mis-matched diluent Lot M9815 does not cause a significant bias. According to our investigation, ECO_2 Quality Control (QC) results may experience a potential bias of up to +0.52 mmol/L and Na^+ QC results may experience a potential bias of up to +1.51 mmol/L.
- VITROS Performance Verifier II (PVII), Lot R1176, incorrectly reconstituted with mis-matched diluent Lot P9967 may lead to:
  1. A shift in QC performance leading to the potential acceptance of a sub-optimal calibration which can impact clinical interpretations and patient management.
  2. Falsely reduced QC results that exceed the Range of Means and with potential bias greater than the Within Laboratory PV SD, which may cause QC failure and a potential delay in testing. According to our investigation, ECO_2 and Na^+ QC results may experience a potential bias of up to -6 mmol/L.

QuidelOrtho recommends a review of ECO_2 and Na^+ QC results generated using VITROS Performance Verifiers, Lots Q1174 and R1176, for any unexpected QC shift. Results exceeding the Range of Means should be investigated.

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. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

As of 27-Feb-2024, QuidelOrtho has received 9 complaints relating to this issue with no reports of adverse events.

REQUIRED ACTIONS

- To ensure your laboratory is using the appropriate diluent for reconstitution, inspect your inventory of VITROS Performance Verifier, Lots Q1174 and R1176.
- If mis-matched diluent Lots M9815 or P9967 are found, render unusable and discard all sales units of VITROS Performance Verifier, Lots Q1174 and R1176.
- Complete the enclosed Confirmation of Receipt form no later than **Month DD, 2024**. Upon receipt of your completed Confirmation of Receipt form, QuidelOrtho will provide credit for, or replacement of, discarded product.
- Review your laboratory's ECO_2 and Na^+ QC results generated using VITROS Performance Verifier, Lots Q1174 and R1176, for any unexpected QC shift.
- Please forward this notification if the affected product was distributed outside of your facility.
- Save this notification with your User Documentation or Post this notification near your laboratory's inventory storage area until an inspection of VITROS Performance Verifier, Lots Q1174 and R1176 has been performed.

Resolution
QuidelOrtho has taken the necessary steps to correct this issue at our manufacturing facility.

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

Insert signatory if applicable in your region.

Enclosure: Confirmation of Receipt form (Ref. CL2024-045_EU_CofR)