

May 2024

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Incorrect Expiration Date Assigned to VITROS® Chemistry Products
Calibrator Kit 29, Lot 2953

Dear Valued Customer,

This notification is to inform you of an issue affecting VITROS® Chemistry Products Calibrator Kit 29, Lot 2953, which was assigned an incorrect expiration date during release.

Product Name	Product Code (Unique Device Identifier)	Affected Lot	Correct Expiry
VITROS Chemistry Products Calibrator Kit 29	680 2344 (10758750002672)	2953	24-Jul-2024
For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 29 is used to calibrate the VITROS 5,1 FS/4600 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems for the quantitative measurement of total iron-binding capacity (TIBC) using VITROS Chemistry Products dTIBC Reagent.			

Summary

QuidelOrtho™ has found that VITROS Chemistry Products Calibrator Kit 29, Lot 2953, was assigned the incorrect expiration date of 24-Jul-2025 during release. The *correct* expiration date for Lot 2953 is **24-Jul-2024**.

The incorrect expiration date is on the product labelling (vials, sales unit cartons, and shipping case labels) and Certificate of Analysis. The correct expiration date appears on the Assay Data Disk (ADD). Please note that the performance of Lot 2953 is *not* affected by this issue (when used by the correct expiration date).

To help assure the product is not used beyond its correct expiry date, QuidelOrtho advises that *upon receipt* of a new lot, customers discontinue using, render unusable, and discard VITROS Chemistry Products Calibrator Kit 29, Lot 2953.

Impact to Results

VITROS Chemistry Products Calibrator Kit 29, Lot 2953 expires on **24-Jul-2024**; until then, QuidelOrtho does not anticipate any impact to results. There is no need to review previously reported QC results generated using VITROS Calibrator Kit 29, Lot 2953, or associated patient results, as the product is currently still in date and results are not affected.

If the lot is used after the *correct* expiration date this may result in a sub-optimal calibration. If daily Quality Control fluids do not detect this, there is a potential for biased TIBC results.

As of 22-May-2024 QuidelOrtho has received zero complaints related to this issue with no reports of adverse events.

REQUIRED ACTIONS

- Discontinue using, render unusable, and discard any remaining inventory of VITROS Chemistry Products Calibrator Kit 29, Lot 2953 by the correct expiration date, 24-Jul-2024.
- Place an order for Calibrator Kit 29.
- If you have previously obtained a Certificate of Analysis, then download a new one from ORTHO PLUS on quidelortho.com.
- To help assure the product is not supported beyond its expiry date, upload ADD DRV 6286 or higher before 24-Jul-2024. Once DRV 6286 or higher has been uploaded the product will no longer be supported and you must use an alternate lot.
- Complete the enclosed Confirmation of Receipt form no later than **7 July 2024**. Upon receipt of your completed Confirmation of Receipt form, QuidelOrtho will provide credit for the quantity indicated on the form.
- Save this notification with your User Documentation or post this notification by each VITROS 5,1 FS/4600/5600/XT 7600 System until the issue has been resolved.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

We apologise for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or the Global Services Organisation.

Sincerely,



Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Enclosure: Confirmation of Receipt form (Ref. CL2024-130_Conf)

To report adverse events, contact your local QuidelOrtho representative or our Global Services Organisation.

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. 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.