QuidelOrtho™

May 2023

URGENT PRODUCT CORRECTION NOTIFICATION

Potential Biased Results using VITROS® Chemistry Products Calibrator Kit 20, Lot 2022

Dear Customer,

QuidelOrtho (formerly Ortho Clinical Diagnostics) recently became aware that VITROS® Chemistry Products Calibrator Kit 20, Lot 2022 has the potential to cause biased results in the upper end of the reportable range for the assays listed in the footnote of the table below. As a result, discontinue using and discard Lot 2022.

Affected Product	Product Code (Unique Device Identifier)	Affected Lot	Expiry
VITROS® Chemistry Products Calibrator Kit 20	6801704 (10758750006687)	2022	06-Sept-2023

Issue Description

VITROS Calibrator Kit 20 contains five calibrator levels. Although Lot 2022 met all initial release criteria, vial to vial variability was subsequently observed during routine internal testing. This prompted an investigation that confirmed that the Level 5 calibrator exhibited vial to vial variability which may cause a bias of varying magnitude for all six affected assays.

Impact to Results

If your laboratory obtains a successful calibration using Lot 2022, performing routine quality control processing may not detect the issue as the bias occurs at the upper end of the assay's measuring range.

The largest biases observed were at elevated concentrations because the Level 5 calibrator is the highest-level calibrator impacted by this issue. Results generated within the reference interval (where clinical evaluations are assessed) are not similarly affected compared to the bias observed in the upper end of each assay's measuring range.

The observed bias for Transferrin at both the lower and upper ends of the reference interval is within 10% and is unlikely to lead to serious injury to the patient.

The observed bias for C3 and C4 at both the lower and upper ends of the reference interval are within 10% and results are unlikely to lead to misdiagnosis or misinterpretation of disease progress.

The observed bias for IgA at both the lower and upper ends of the reference interval is within 10% and not likely to result in misdiagnosis leading to clinically significant risks.

Impact to Results (Cont'd)

The observed bias for IgG at both the lower and upper ends of the reference interval is within 10% and would likely not alter clinical decisions but may create diagnostic confusion.

The observed bias for IgM at the lower end of the reference interval is within 10% and unlikely to miss the diagnosis of immune deficiency, however the observed bias at the upper end of the reference interval is around 30% and may cause confusion and trigger additional tests but is unlikely to pose a serious health risk.

Transferrin, C3, C4, IgA, IgG, and IgM tests are not considered to be urgent tests, and a delayed result is unlikely to cause serious patient injury.

Refer to the Questions and Answers section for information on the observed bias for each assay.

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 you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

As of 13-Apr-2023 QuidelOrtho has received 33 complaints, with no reports of injury or death, related to this issue.

REQUIRED ACTIONS

- Immediately discontinue using and discard your remaining inventory of VITROS Calibrator Kit 20, Lot 2022. QuidelOrtho will credit your account. Indicate quantities to be credited on the attached Confirmation of Receipt form.
- If you do not have an alternative lot of VITROS Calibrator Kit 20, you must discontinue reporting patient results that were derived using a Lot 2022 calibration.
- Use an alternative lot of VITROS Calibrator Kit 20 to re-calibrate VITROS Transferrin, C3, C4, IgA, IgG and/or IgM assays on your VITROS System(s).
- Complete the enclosed Confirmation of Receipt form no later than **24 May 2023**.
- Please forward this notification if the affected product was distributed outside of your facility.
- Post this notification by your VITROS System(s) or with the user documentation until you receive your replacement order.

Resolution

Once we receive your completed Confirmation of Receipt form, QuidelOrtho will process the credit to your account.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or our Ortho Care™ Technical Solutions Centre.

Sincerely,

Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Enclosure: Confirmation of Receipt Form (Ref. CL2023-107 Conf)

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.