



# URGENT

Ortho Clinical Diagnostics

May DD, 2023

## URGENT FIELD SAFETY NOTICE

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

Dear Valued 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 supported 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
VITROS Chemistry Products Calibrator Kit 20 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 Transferrin, C3, C4, IgA, IgG and IgM.			

#### 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 for all six affected assays, although to varying magnitudes.

#### 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.

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.



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### Impact to Results (Cont'd)

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Transferrin, C3, C4, IgA, IgG, and IgM tests are not STAT 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

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- Immediately discontinue using and discard your remaining inventory of VITROS Calibrator Kit 20, Lot 2022. QuidelOrtho will replace or credit your account. Indicate quantities to be replaced or 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 using a Lot 2022 calibration.
- Upon receipt of your replacement lot of VITROS Calibrator Kit 20, re-calibrate VITROS Transferrin, C3, C4, IgA, IgG and/or IgM assays on your VITROS System.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY**.
- 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

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Once we receive your completed Confirmation of Receipt form, QuidelOrtho will process your replacement order or credit your account. To provide replacement product for all customers, product allocation may be necessary.

### Contact Information

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We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact our Ortho Care Technical Solutions Center at **Insert phone number**.

**Insert signatory if applicable.**

Enclosure: Confirmation of Receipt Form (Ref. CL2023-107\_EU\_CofR)



### Questions and Answers

#### 1. What is the expected bias for results if using an affected vial of VITROS Calibrator Kit 20, Lot 2022?

Because this issue is due to the vial-to-vial variability for Calibrator Level 5 of Lot 2022, each calibration event may be affected differently. Based upon our internal testing, the table below shows the magnitude of biases observed between calibrations generated using different vials of Lot 2022. Your laboratory's results may differ in performance due to vial-to-vial and other sources of variability.

Assay	Concentration Range (mg/dL) Conventional Units	Average Bias Observed	Maximum Bias Observed
IgA	40 - 200	7.4%	7.7%
	200 - 450	3.3%	3.7%
	450 - 800	21.4%	26.0%
IgG	270 - 1000	7.4%	8.2%
	1000 - 2000	3.9%	6.0%
	2000 - 2700	12.5%	14.6%
IgM	25 - 150	6.3%	7.3%
	150 - 230	3.5%	4.2%
	230 - 400	5.4%	5.7%
C3	40 - 180	3.1%	6.2%
	180 - 300	3.9%	5.0%
	300 - 380	19.4%	20.9%
C4	8 - 45	4.6%	7.2%
	45 - 60	3.6%	4.1%
TRFRN	80 - 300	11.1%	12.3%
	300 - 550	6.7%	7.7%
	550 - 750	13.2%	16.3%



## Questions and Answers (Cont'd)

Assay (Units)	Concentration Range SI Units	Average Bias Observed	Maximum Bias Observed
<b>IgA</b> (g/L)	0.40 - 2.00	7.4%	7.7%
	2.00 - 4.50	3.3%	3.7%
	4.50 - 8.00	21.4%	26.0%
<b>IgG</b> (g/L)	2.70 - 10.00	7.4%	8.2%
	10.00 - 20.00	3.9%	6.0%
	20.00 - 27.00	12.5%	14.6%
<b>IgM</b> (g/L)	0.25 - 1.50	6.3%	7.3%
	1.50 - 2.30	3.5%	4.2%
	2.30 - 4.00	5.4%	5.7%
<b>C3</b> (mg/L)	400 - 1800	3.1%	6.2%
	1800 - 3000	3.9%	5.0%
	3000 - 3800	19.4%	20.9%
<b>C4</b> (mg/L)	80 - 450	4.6%	7.2%
	450 - 600	3.6%	4.1%
<b>TRFRN</b> (g/L)	0.80 - 3.00	11.1%	12.3%
	3.00 - 5.50	6.7%	7.7%
	5.50 - 7.50	13.2%	16.3%

**2. Can I continue to use VITROS Calibrator Kit 20, Lot 2022 until I receive a replacement?**

No, since a calibration performed using Lot 2022 has the potential to cause biased results, VITROS Calibrator Kit 20, Lot 2022, must be discarded.

**3. Will my VITROS System fail the calibration if using an affected vial of VITROS Calibrator Kit 20, Lot 2022?**

No. The VITROS System may generate a successful calibration curve without generating any condition codes even if using an affected vial of Lot 2022.

**4. Will this issue be detected by performing routine Quality Control testing?**

No. This issue may not be detected by performing routine Quality Control testing.

**5. Can QuidelOrtho perform an evaluation of my calibration data to determine if my results were affected?**

Due to the variability across all VITROS Systems, we cannot reliably determine if your current calibration, performed using an affected vial of Lot 2022, has been impacted by this issue.



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## **Questions and Answers (Cont'd)**

**6. How soon can I expect replacement?**

As soon as we receive your completed Confirmation of Receipt form, a replacement order will be expedited. Product is on allocation to ensure availability for all customers.

**7. How do I know that the replacement lot that I receive will not be affected by this issue?**

QuidelOrtho has identified certain factors that may correlate to this issue, and we are monitoring newly manufactured lots for this occurrence.