

April 2024

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**Potential for Positive Bias When Using VITROS® Immunodiagnostic Products Free T3 Reagent Pack**

Dear Valued Customer,

This notification is to inform you that QuidelOrtho™ has confirmed an issue involving VITROS® Immunodiagnostic Products Free T3 Reagent Pack, where some lots (listed below) may produce positively biased results.

Affected Product Name	Product Code (Unique Device Identifier)	Affected Lots	Expiry
VITROS Immunodiagnostic Products Free T3 Reagent Pack	131 5589 (10758750008797)	3042	09-Apr-2024
		3052	02-May-2024
		3061	03-Jun-2024
		3080	02-May-2024
VITROS Immunodiagnostic Products Free T3 Calibrators	111 2820 (10758750008438)	3090	14-Jun-2024
		3100	29-Jul-2024
		3110	13-Aug-2024
		3126	04-Sep-2024

**Summary**

QuidelOrtho has received complaints of higher-than-expected Free T3 (FT3) results when using the affected lots of VITROS Free T3 Reagent Pack listed above. Our investigation found that, when processing Quality Control (QC) and patient samples with the lots listed above, results may be positively biased. The bias will vary depending on the lot. The table on page 2 shows the potential percentage of positive bias, for each lot, from our in-house control concentration of 4.55 pmol/L.

Customers are advised to discontinue using, render unusable, and discard the affected lots of VITROS Free T3 Reagent Pack (and associated calibrators). QuidelOrtho will provide credit or replacement of discarded product.

Please note that only the lots identified in this notification are affected by this issue.

VITROS Free T3 Lot	% Bias At a Concentration of 4.55 pmol/L
3042	23.9%
3052	27.7%
3061	14.7%
3080	27.6%
3090	14.9%
3100	19.9%
3110	17.4%
3126	14.9%

**Impact to Results**

This issue may be detected when performing QC, as QC results generated using the affected lot(s) may be positively biased outside the established QC range. However, the issue may *not* be detected if the baseline mean for the QC material used with the affected lot(s) of VITROS Free T3 Reagent Pack has been adjusted.

The issue may also be detected by the observation of abnormal patient results.

Using an affected lot of VITROS Free T3 Reagent Pack may cause positively biased results which may impact patient management to a varying degree, depending on the magnitude of the bias observed, clinical assessment, and the results of other thyroid function tests. In the worst-case scenario:

- Positively biased QC results outside the acceptable control limits may result in QC troubleshooting/investigation, potentially causing delays in patient sample testing or result reporting.
- Positively biased patient results may result in diagnostic confusion when discordant with the results of other thyroid function tests (such as TSH and Free T4). Where Free T3 is used singly to monitor the early stage of antithyroid drug therapy in patients with hyperthyroidism, the potential for an impact to treatment is increased.

QuidelOrtho does not recommend a review of previously reported results. A review may not detect falsely elevated patient results and, even if detected, is unlikely to significantly impact patient management.

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 03-Apr-2024, QuidelOrtho has received 160 complaints relating to this issue with no reports of adverse events.

**REQUIRED ACTIONS**

- Discontinue using, render unusable, and discard affected lots of VITROS Free T3 Reagent Pack (and associated calibrators).
- If required, place an order for new product.
- Complete the enclosed Confirmation of Receipt form no later than **25 April 2024**. Upon receipt of your completed form, QuidelOrtho will provide credit for discarded product.
- Save this notification with your User Documentation or post this notification by each VITROS ECi/ECiQ/3600/5600/XT 7600 System until the issue has been resolved.
- Please forward this notification if the affected product was distributed outside of your facility.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local QuidelOrtho representative or our Global Services Organisation.

**Resolution**

QuidelOrtho's investigation is on-going, and we are currently working to identify root cause.

**Contact Information**

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

Sincerely,



Kevin Davies  
Regional Product Support Manager (ASEAN & Korea)

Enclosure: Confirmation of Receipt form (Ref. CL2024-081\_Conf)

## Questions and Answers

**1. Are other lots of VITROS Free T3 Reagent Pack affected by this issue?**

No, only the lots listed in this notification contain the potential to experience positively biased results. QuidelOrtho has reviewed the release specifications and made the appropriate adjustments to prevent this issue from occurring in other lots.

**2. Will I see a shift in performance after switching to a non-affected lot of VITROS Free T3 Reagent Pack?**

Yes, customers may notice a negative shift in QC performance when switching to an unaffected lot of VITROS Free T3 Reagent Pack.