QuidelOrtho™

URGENT

Month DD, 2024

URGENT FIELD SAFETY NOTICE

VITROS® Immunodiagnostic Products Anti-HBs Calibrators Instability May Lead to Positively Biased Patient and Quality Control Results

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue affecting certain lots (listed below) of VITROS® Immunodiagnostic Products Anti-HBs Calibrators, which will experience a signal reduction over the shelf life of the product potentially leading to positively biased Patient and/or Quality Control (QC) results.

Product Name	Product Code (Unique Device Identifier)	Affected Lots	Expiry Date	Manufacture Date
VITROS Immunodiagnostic Products Anti-HBs Calibrators	152 4693 (10758750006533)	5111	21-Jun-2024	12-Oct-2023
VITROS Immunodiagnostic Products Anti-HBs Reagent Pack	178 7753 (10758750006502)	5120	01-Aug-2024	09-Nov-2023
For *in vitro* diagnostic use only. For use in the calibration of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems for the quantitative measurement of anti-HBs in human serum and plasma (heparin or citrate).				

Summary

QuidelOrtho's internal stability testing of VITROS Anti-HBs Calibrators detected a gradual reduction in calibration signal for Calibrator Levels 2 and 3 over the shelf life of the product for the lots listed above. This reduction in signal may affect the shape of the calibration curve generated during calibration, compared to the calibration curve generated earlier in the product's shelf life.

A change in the shape of the calibration curve may cause patient and QC samples tested using the associated VITROS® Immunodiagnostic Products Anti-HBs Reagent Pack to report results as falsely elevated, potentially causing Negative results to report as Borderline, and Borderline results to report as Positive.

This issue is detectable by performing QC as results generated will be higher than expected and/or outside the expected limits for QC, depending on the age of the lot and amount of signal reduction experienced in Calibrator Levels 2 and 3.

QuidelOrtho advises customers to discontinue using, render unusable, and discard the affected lots of VITROS Anti-HBs Calibrators and associated Reagent Pack listed in this notification. QuidelOrtho will provide replacement or credit for discarded lots.

Impact to Results
This issue may lead to positively biased patient and QC results due to the reduced calibrator signals in Calibrator Levels 2 and 3.

The table below demonstrates the bias observed for results generated during our investigation of the affected lots. Please note that as this issue is related to calibrator signal reduction over the shelf life of the product, QuidelOrtho estimates an increase in the observed bias over time.

Lot Number	Age From Manufacture Date (In Weeks)	Average % Bias (+) Observed
5111	25	35
5120	21	10

Positively biased QC results may be outside the expected QC limits, leading to QC failure and potentially causing a delay in patient testing. However, this delay is unlikely to impact patient management due to the clinical utility of Anti-HBs, as described in the Intended Use in the Instructions For Use (IFU) of this product.

Falsely elevated patient results may breach the clinical thresholds, causing Negative results to report as Borderline, and Borderline results to report as Positive. Refer to the VITROS Anti-HBs Reagent Pack and Calibrators IFU for guidance on the interpretation of Borderline results.

A false positive result may lead to an erroneous assessment of the patient's immunity to Hepatitis B, potentially resulting in the patient not receiving the Hepatitis B vaccine, Hepatitis B Immune Globulin, or appropriate counseling, which may increase the patient's risk of contracting the Hepatitis B virus.

QuidelOrtho recommends a review of previous results between 12 -17 mIU/mL, generated using the associated lot(s) of VITROS Anti-HBs Reagent Pack, where only Anti-HBs testing was performed and was positive (for example, post-vaccination testing) or where only Anti-HBs was positive in the triple-panel test (Anti-HBs, HBsAg, anti-HBc). Please review the Questions and Answers section at the end of this notification for more information.

As of 09-May-2024 QuidelOrtho has received 22 complaints relating to this issue with no reports of adverse events.

REQUIRED ACTIONS

- Discontinue using, render unusable, and discard the affected lots of VITROS Anti-HBs Calibrators and associated Reagent Pack remaining in your inventory.
- Complete and return 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 or replacement for your discarded inventory.
- 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 Global Services Organization.

Resolution
QuidelOrtho has identified the root cause to be related to a specific raw material used in the manufacture of VITROS Anti-HBs Calibrators. Only the lots identified in this notification are affected by this issue.

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

Insert signatory if applicable in your region.

Enclosure: Confirmation of Receipt form (Ref. CL2024-118_EU_CofR)

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Questions and Answers

1. **Is this issue related to the issue described in the previous notification, CL2023-272_EU, titled, 'Certain Lots of VITROS Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators May Experience Increased Calibration Failures or an Increase in Falsely Elevated Results'?**

   No, while some details of this issue may be similar, this issue is **not** a continuation of the issue described in the previous notification which involved the potential for calibration failure and random imprecision.

2. **How can I tell if my calibration is biased?**

   Performing QC testing can determine if a biased calibration was accepted, as results will display a positive shift.

3. **Why does QuidelOrtho recommend a review of previous results between 12-17 mIU/mL?**

   QuidelOrtho recommends a review of results within this range as it represents a 40% bias range from which Borderline results could be interpreted as Positive.