QuidelOrtho™

URGENT

Month XX, 2023

URGENT FIELD SAFETY NOTICE

Certain Lots of VITROS Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators May Experience Increased Calibration Failures or an Increase in Falsely Elevated Results

Dear Valued Customer,

The purpose of this notification is to inform you that the lots of VITROS Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators listed below may experience an increased frequency of calibration failures, increased imprecision for quality control and patient samples and may, in some cases, experience falsely elevated results.

Product Name	**Product Code** (Unique Device Identifier)	**Affected Lot(s)**	**Expiry**
VITROS Immunodiagnostic Products Anti-HBs Reagent Pack	1787753 (10758750006502)	5051 5060 5070 5081 5090 5100	26-Dec-2023 13-Jan-2024 28-Jan-2024 06-Apr-2024 07-May-2024 04-Jun-2024
VITROS Immunodiagnostic Products Anti-HBs Calibrators	1524693 (1075875000633)		

Summary

Ortho Clinical Diagnostics (QuidelOrtho™) observed an increase in complaints and performed an investigation which confirmed that customers using the lots of VITROS Anti-HBs Reagent Pack/Calibrators listed above may experience an increase in calibration failures or an increase in imprecision for the negative quality control and patient samples if a successful calibration is performed. QuidelOrtho also received one customer complaint regarding a falsely elevated result which was generated using an affected lot. Customers are advised to discontinue using, render unusable, and discard the affected lots of VITROS Anti-HBs Reagent Pack/Calibrator listed in this notification. QuidelOrtho will provide replacement or credit for discarded lots.

Impact to Results

Scenario 1: Calibration failures will result in the inability to use VITROS Anti-HBs Reagent Pack for patient testing until a successful calibration is performed.

Scenario 2: A successful calibration is performed. This issue may lead to potential, random imprecision when processing patient or quality control samples. Results may be falsely elevated and fall outside control limits however, patient samples which generate elevated results are unlikely to produce the same result when re-tested.

Potential falsely elevated results may exceed the cut-off value defined in the Instructions

Impact to Results (Cont.)
For Use (IFU). If results surpass the "Negative" result threshold and cause a "Borderline" result to be reported, serious patient injury is unlikely. This failure mode is unlikely to be repeatable and repeat testing will likely generate an accurate result. In this case, the risk of serious patient harm is remote.

If a falsely elevated result surpasses the cut-off value (defined in the IFU) and results in a false positive anti-HBs result, the risk of serious patient injury is not remote. Anti-HBs is routinely tested alongside hepatitis B surface antigen (HBsAg) and hepatitis B core antigen antibodies (anti-HBc) as a serological triple-panel for assessment of postvaccination immunity in a group of susceptible individuals or routine screening test. A false positive anti-HBs with negative HBsAg and anti-HBc indicates that the individual is immune to HBV due to vaccination or passive transfer of antibodies from hepatitis B immune globulin (HBIG). In this scenario, the individual would not receive vaccination, making them susceptible to HBV infection. Acute HBV infection may be self-limiting and may not require treatment with an anti-viral agent; however, in some patients, an acute infection may persist, leading to chronic liver disease. If the patient tested positive for all the tests (HBsAg, anti-HBc, and anti-HBs), this result may be initially confusing, though there are reports of the coexistence of HBsAg and
anti-HBs. Those patients would be assessed as acutely infected, requiring further testing and follow-up. Similarly, a patient with no vaccination history but positive anti-HBs and negative anti-HBc would arouse suspicion. Such a scenario would lead to retesting of the patient for confirmation.

In routine hepatitis B screening, anti-HBs testing is done alongside HBsAg and anti-HBc with multiple possible interpretations. In individuals with a positive anti-HBc or HBsAg test, the risk of misdiagnosis or harm to patients due to this failure mode is unlikely. In this scenario, a review of previously reported anti-HBs results is not recommended.

QuidelOrtho recommends a review of previous results between 12-30 mIU/mL, which were generated using an affected lot of VITROS anti-HBs Reagent Pack, where only anti-HBs testing was performed and was positive (for example, postvaccination testing) or where only anti-HBs was positive in the triple-panel test. Please review the Questions & Answers section at the end of this notification for more information.

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 17-Nov-2023, QuidelOrtho has received 51 complaints related to this issue with only 1 complaint related to a falsely elevated (positive) result.

REQUIRED ACTIONS

- Immediately discontinue using, render unusable, and discard all affected lots of VITROS Anti-HBs Reagent Pack/Calibrator in your inventory.
- Ensure your laboratory is following the guidance provided in the Instructions For Use and/or local regulatory requirements.
- Complete the enclosed Confirmation of Receipt form no later than **Month, DD 2023**. Upon receipt of your completed Confirmation of Receipt form, QuidelOrtho will provide credit or replacement of your discarded inventory.
- Upon receipt of your replacement lot of VITROS Anti-HBs Reagent Pack and Calibrator, re-calibrate your VITROS System(s).
- Save this notification with your User Documentation or post this notification by each VITROS ECi/ECiQ/3600/5600/XT 7600 System until this issue has been resolved.
- Please forward this notification if the affected product was distributed outside of your facility.

Resolution

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

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact our Global Services Organization (formerly Ortho Care) at insert phone number.

Insert signatory if applicable.

Enclosure: Confirmation of Receipt Form (Ref. CL2023-272_EU_CofR)

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Questions and Answers

1. **Is the performance of all lots identified in this notification affected similarly?**

   No, due to the stability-related nature of the issue, older affected lots have an increased potential to be impacted by these issues.

2. **Why does QuidelOrtho recommend a review of previous results generated between 12-30 mIU/mL?**

   QuidelOrtho's recommendation is based on the observed performance of the affected lots during this investigation, including 1 customer complaint of false positive outlier results and 1 false positive outlier result observed during our investigation. Please note that QuidelOrtho's investigation includes a data set of 1284 test results of Negative material.