

May 2023

URGENT PRODUCT CORRECTION NOTIFICATION

Revised Storage Instructions for VITROS® Immunodiagnostic Products HBeAg Calibrators

Dear Customer,

QuidelOrtho (formerly Ortho Clinical Diagnostics) has become aware that due to a change in a raw material, VITROS® Immunodiagnostic Products HBeAg Calibrator, Lots 4880 and above, do not meet the current opened - reconstituted stability specification.

Product Name	Product Code (Unique Device Identifier)	Affected Lot(s)	Expiry
VITROS® Immunodiagnostic Products HBeAg Calibrator	1914498 (10758750000234)	4880 & Above	26 Mar 2024

Issue Description

During the manufacture of Lots 4880 and above, QuidelOrtho used a new lot of raw material. Our data has found that the new lots are not stable when opened and the reconstituted vials are stored in the refrigerator for the 5 week period as stated in the Instructions for Use (IFU).

***NOTE: All current lots are NOT affected by this change in raw material.**

This change will affect Lots 4880 and above which will begin shipping in May 2023.

Background Information

The VITROS Immunodiagnostic Products HBeAg Calibrator IFU currently contains the following storage specifications:

Calibrator Storage and Preparation

Calibrator	Storage Condition	Stability
Unopened	Refrigerated 2–8 °C (36–46 °F)	Expiration Date
Opened - Reconstituted	Refrigerated 2–8 °C (36–46 °F)	≤5 weeks
Opened - Reconstituted	Frozen ≤-20 °C (≤-4 °F)	≤13 weeks
Opened -Reconstituted calibrators may be stored frozen. Do not freeze-thaw more than once.		

Impact to Results

Our data indicates that if the VITROS HBeAg Calibrators, Lots 4880 and above are stored refrigerated, calibration may fail and/or Quality Control testing may be outside of established ranges. If a successful calibration occurs, false positive results may be generated.

Resolution

As stated in the Instructions for Use, it is acceptable to store VITROS HBeAg Calibrators:

Unopened and refrigerated 2–8 °C (36–46 °F) until its expiration date

or

Opened and reconstituted then frozen ≤ -20 °C (≤ -4 °F) for up to 13 weeks

As a result of the change in raw material, opened and reconstituted vials for Lots 4880 and above can now only be used or stored refrigerated at 2–8 °C (36–46 °F) for up to 2 hours.

QuidelOrtho cannot offer product replacement as this raw material change affects all new and future lots manufactured. We will issue a follow-up communication if our data suggests additional changes are required.

REQUIRED ACTIONS

- Opened and reconstituted vials **for Lots 4880 and above** can only be used or stored refrigerated for up to 2 hours.
- Complete the enclosed Confirmation of Receipt form no later than **22 May 2023**.
- Forward this notification if any of the affected lots of VITROS HBeAg Calibrators were distributed outside of your facility.
- Save this notification with your user documentation or post this notification by each VITROS System.

Technical Bulletin

QuidelOrtho is working with our supplier to identify the root cause of this issue. In the interim, we will issue a Technical Bulletin that will also contain the information provided in this notification. We will also update the Instructions for Use pending notifications and registrations as needed.

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)

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.