



November 2018

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Revised Instructions for VITROS Immunodiagnostic Products Myoglobin Calibrators

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

Ortho Clinical Diagnostics has been alerted to calibration failures and biased results when using VITROS® Immunodiagnostic Products Myoglobin Calibrators.

Affected Product	Product Code (Unique ID No.)	Affected Lots (Expiry)
VITROS® Immunodiagnostic Products Myoglobin Calibrators	6801043 (10758750001026)	Lots 1271 through 1310 (expired)
		Lots 1315 & Above (in-date)

Description of Issue

Ortho has become aware of a stability issue with VITROS Myoglobin Calibrators that may cause calibration failures or atypical Quality Control (QC) results following a successful calibration.

Our investigation found that the calibrator signal decreases significantly during the claimed 24 hour stability limit of reconstituted calibrators.

Impact to Results

When the calibrators are reconstituted and used within the first 2 hours or after more than 4 hours, the following may be observed:

- Unsuccessful calibration due to a Calibrator Signal Index (CSI) failure. When this occurs, the system alerts the operator with an appropriate condition code:
 - For VITROS 3600/5600/XT 7600 Systems: PW7-012 (Calibrator signal index above limit Level %d)
 - For VITROS ECi/ECiQ Systems: 542-037 (Calibration %s Lot %s failed: the signal index was out of range)
- Biased results of up to $\pm 15\%$ depending on the amount of time the reconstituted calibrators are stored at room temperature prior to calibration.

Resolution

To optimize calibrator performance, Ortho is providing a revision to the calibrator storage and preparation instructions in the Instructions for Use (IFU) for all current and future lots of VITROS Myoglobin Calibrators.

The revised calibrator instruction may be a temporary resolution. A permanent resolution will be identified pending the outcome of our ongoing investigation. In the interim, we will issue a follow up notification with additional information upon availability.

REQUIRED ACTIONS

Until further notice from Ortho, use the following instructions for VITROS Myoglobin Calibrators:

- Reconstitute the calibrators using 1.0 mL distilled water, as per the Instructions for Use.
- **Allow reconstituted calibrator vials to stand at room temperature for 2 hours and then proceed with calibration within 2 hours (4 hours total).**
- **Discard reconstituted calibrators after a maximum of 4 hours.**

REQUIRED ACTIONS (continued)

- Acknowledge the information contained in this notification by completing and submitting the Confirmation of Receipt form no later than **December 14, 2018**.
- Post this notification by each VITROS System at your facility that processes this assay or with the user documentation.
- Please forward this notification if the product was distributed outside of your facility.

Current Instructions

The instructions for use (IFU) currently contain the following handling and storage information for VITROS Myoglobin Calibrators:

- Mix thoroughly by inversion and bring to 15–30 °C (59–86 °F) before use.
- Handle calibrators in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time calibrators are on the system. Return to 2–8 °C (36–46 °F) as soon as possible after use, or load only sufficient for a single determination.
- Calibrators may be left on the system for a maximum of 2 cumulative hours.

Calibrator	Storage Condition	Stability
Unopened	Refrigerated: 2–8 °C (36–46 °F)	Expiration Date
Opened - Reconstituted	Refrigerated: 2–8 °C (36–46 °F)	≤24 hours
VITROS Myoglobin Calibrators are freeze-dried and are reconstituted with 1.0 mL distilled water.		

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.