

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Incorrect Barcode Labels for VITROS® Chemistry Products
Calibrator Kit 25, Lot 2576**Date** **October 2016****Issue** This notification provides information regarding the barcode labels included in VITROS Chemistry Products Calibrator Kit 25, Lot 2576.

Some of the barcodes included in the carton incorrectly indicate the Lot as 2575 instead of the correct Lot 2576.

Affected Products

Product Name (Unique Device Identifier No.)	Product Code	Affected Lot No. (Expiry Date)
VITROS Chemistry Products Calibrator Kit 25 (10758750001675)	6801896	Lot 2576 (2017-09-02)

VITROS Calibrator Kit 25 is used to calibrate VITROS Systems for the quantitative measurement of HDL cholesterol using VITROS Chemistry Products dHDL Slides.

Description Printed barcode labels are included with VITROS Calibrator Kits. They are used with the automatic calibration feature when calibrating VITROS 4600 or 5600 Systems.

NOTE: Automatic calibration is not supported on VITROS 250/350 or 5,1 FS Systems.

Ortho Clinical Diagnostics (Ortho) confirmed that barcode labels included in some VITROS Calibrator Kit 25, Lot 2576 cartons contain an incorrect lot number. The labels indicate Lot 2575 instead of the correct Lot 2576 for all three levels as shown below:



When the operator attempts to use the affected barcode labels to calibrate VITROS dHDL Slides, a 'PZC-006' condition code occurs, indicating that the Calibrator Lot is not supported by the Assay Data Disk (ADD); therefore the calibration is not successful.

NOTE: All labelling on the calibrator vials and the carton is correct. Lot 2576 calibrators perform as expected if the operator *manually* programs the correct lot information for calibration.

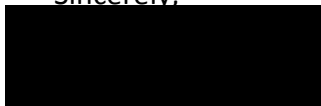
Required Actions

- Inspect the barcode labels provided in VITROS Calibrator Kit 25, Lot 2576.
- If the barcode labels indicate Lot 2575 instead of Lot 2576, discard the affected labels and manually program Lot 2576 when calibrating VITROS dHDL Slides.
- Complete the Confirmation of Receipt form now to register receipt of the notification. Please return the completed form by **October 21, 2016**.

**Contact
Information**

We apologize for any inconvenience this may have caused your laboratory. If you have questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Sincerely,



Jon Wong
QA Manager

Enclosure: Confirmation of Receipt Form