



IMPORTANT

Ortho Clinical Diagnostics

January 2018

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Unsuccessful Calibration using VITROS® Immunodiagnostic Products TSH Reagent Packs

Dear Customer,

This notification provides information regarding the potential inability to obtain a successful calibration when using VITROS TSH Reagent Packs, Lot 5430. Our records indicate that you were shipped the affected lot.

Product Name	Product Code (Unique Device Identifier No.)	Affected Lot No. (Expiry Date)
VITROS Immunodiagnostic Products TSH Reagent Pack	1912997 (10758750000227)	Lot 5430 (01-Mar-2018)

Description of Issue

Ortho Clinical Diagnostics (Ortho) has confirmed that VITROS TSH Reagent Packs, Lot 5430 exhibits an increase in the frequency of calibration failures. Ortho's investigation, based on e-Connectivity analysis, indicates that calibration of the affected lot is successful on a majority of VITROS Systems. VITROS TSH Reagent Packs, Lot 5430 met all quality assurance specifications upon release.

Resolution

If your laboratory is able to successfully calibrate VITROS TSH Reagent Packs, Lot 5430 and your quality control results are acceptable; you may continue using your existing inventory.

If you are unable to calibrate, Ortho will issue credit for your remaining inventory of Lot 5430. Please discard your remaining inventory upon receipt of replacement product.

Impact to Results

Previously reported patient results are valid providing that quality control results were within acceptable limits.

REQUIRED ACTIONS

- If you are unable to calibrate VITROS TSH Reagent Packs, Lot 5430, Ortho will credit your account as indicated on your Confirmation of Receipt form.
***NOTE:** If you have a successful calibration, and quality control results are acceptable, it is acceptable to continue using the affected lots.*
- Post this notification by each system that processes VITROS TSH Reagent Packs, Lot 5430.
- Complete the Confirmation of Receipt form now to register receipt of the notification. All customers should return the completed form by **January 29, 2018**.
- In the future, if you decide to discontinue using Lot 5430, resubmit the Confirmation of Receipt form to indicate the quantity to be credited.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho CareTM Technical Solutions Centre at 1800-5646-766.

Sincerely,



Jon Wong, 19 Jan 2018

QA Manager