



IMPORTANT

Ortho Clinical Diagnostics

September 2018

IMPORTANT PRODUCT CORRECTION NOTIFICATION **Increased Frequency of Calibration Failures using** **VITROS® Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2**

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

This notification provides information regarding the potential increased frequency of calibration failures when using VITROS Vitamin B12 Reagent Packs, Lot 2601. Our records indicate that you were shipped the affected lot.

Affected Product	Product Code (Unique Device Identifier No.)	Affected Lot	Expiry Date
VITROS® Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2	1453489	Lot 2601	06-APR-2019

Investigation

Ortho Clinical Diagnostics confirmed that VITROS Vitamin B12 Reagent Pack 1/2, Lot 2601 exhibits the potential for an increased frequency of calibration failures. When a calibration failure occurs, customers have reported that their VITROS System generated the following condition codes to indicate that the calibrator signal index exceeds the limit:

- For VITROS 3600/5600/XT 7600 Systems: PW7-012 (Calibrator signal index above limit Level %d)
- For VITROS ECi/ECiQ Systems: 542-037 (542-037: Calibration %s Lot %s failed)

Our preliminary testing indicates that the calibration failure is related to a component used during the manufacture of some VITROS Vitamin B12 Reagent Packs 1/2, Lot 2601 and is not associated with VITROS Vitamin B12 Calibrators. **Note:** Not all reagent packs from Lot 2601 are affected.

Resolution

Because only a subset of the Reagent Packs are affected and they are not readily identifiable, Ortho will credit your account for your remaining inventory of VITROS Vitamin B12 Reagent Pack 1/2 and Calibrators for Lot 2601. In order to supply product for all customers, product allocation may be necessary.

If your laboratory is able to successfully calibrate Lot 2601 and your quality control results are acceptable; you may continue using your existing inventory until new product arrives. In the interim, you are advised to perform quality control testing on every reagent pack when using Lot 2601.

Impact to Results

If a successful calibration is obtained, quality control results may not identify this issue. Since not all reagent packs are affected, the table below shows the potential impact to results:

Reagent Pack used for Calibration	Reagent Pack used for Sample Results	Impact to Results
Unaffected Reagent Pack	Affected Reagent Pack	Positive bias (>20%)
Affected Reagent Pack	Unaffected Reagent Pack	Negative bias (<20%)
Affected Reagent Pack	Affected Reagent Pack	No impact
Unaffected Reagent Pack	Unaffected Reagent Pack	No impact

REQUIRED ACTIONS

- Place an order for new product.
- If this lot was successfully calibrated and your quality control results are acceptable; you may continue using your existing inventory of VITROS Vitamin B12 Reagent Pack 1/2 Lot 2601 until new product arrives. We advise that you perform quality control on every reagent pack.
- If this lot cannot be successfully calibrated, contact our Ortho Care™ Technical Solutions Centre.
- Complete the Confirmation of Receipt form and return by **September 7, 2018**.
- Discontinue using Lot 2601 upon receipt of new product.
- Post this notification by each system that processes VITROS Vitamin B12 Reagent Pack 1/2.
- Forward this notification if the product was distributed outside of your facility.

Contact Information

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