



October 2018

IMPORTANT UPDATE: PRODUCT CORRECTION NOTIFICATION**Shift in Results using VITROS® Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2**

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

This notification provides updated information regarding a potential shift in results obtained when using the specific lots of VITROS Vitamin B12 Reagent listed below. Our records indicate that you were shipped an affected lot.

Affected Product	Product Code (Unique ID No.)	Lot No.	Expiry Date
VITROS® Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2	1453489 (10758750009138)	2610	10-Apr-2019
		2620	16-Apr-2019

Issue Description

Previously, Ortho Clinical Diagnostics determined that a subset of the reagent packs for Lot 2601 had prolonged exposure during the manufacturing process causing a shift in results that can be positive or negative.

Ortho has now confirmed that Lots 2610 and 2620 are similarly affected.

Impact to Results

The impact to results is shown below.

Reagent Pack 1 used for Calibration	Reagent Pack 1 used for Sample Results	Impact to Results
Unaffected Reagent Pack	Affected Reagent Pack	Positive bias of >20%
Affected Reagent Pack	Unaffected Reagent Pack	Negative bias of >20%
Affected Reagent Pack	Affected Reagent Pack	No impact
Unaffected Reagent Pack	Unaffected Reagent Pack	No impact

REQUIRED ACTIONS**To continue using VITROS Vitamin B12, Lots 2610 and 2620:**

- Only have one Reagent Pack 1 on board your system at a time.
- Perform Quality Control (QC) testing on **each** Reagent Pack 1.
- If the quality control results are outside of the established ranges, discard the pack and repeat QC testing using a new pack.
- If the repeated QC results remain outside of established ranges, recalibrate using the same new pack.
- If QC results continue to be outside of established ranges, contact the Ortho Care™ Technical Solutions Centre for assistance.

NOTE: If you do not wish to continue using the affected lots, Ortho will issue credit for your remaining inventory of Lots 2610 and/or 2620 if requested on your Confirmation of Receipt form. In order to supply product for all customers, product allocation may be necessary.

ADDITIONAL REQUIRED ACTIONS

- Post this notification by each system that processes VITROS Vitamin B12 Reagent, Lots 2610 and/or 2620.
- Complete the Confirmation of Receipt form and return by **November 1, 2018**.
- Forward this notification if you have distributed these products outside of your facility.

Resolution

Ortho has taken steps to help ensure that reagent components have limited exposure to light during the manufacturing process.

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 Care[™] Technical Solutions Centre at 1800 5646766.