Ortho Clinical Diagnostics	**IMPORTANT PRODUCT CORRECTION NOTIFICATION** **Biased Results using Three Lots of** **VITROS® Chemistry Products VANC Reagent**

Date Issued February 2017

Affected Product

Name (Unique Identifier No.)	Product Code	Affected Lot Numbers	Expiry Dates
VITROS Chemistry Products VANC Reagent (10758750006731)	6801709	31-5407	2017-05-23
		31-5474	2017-07-04
		31-5506	2017-07-04

Issue

Ortho Clinical Diagnostics (Ortho) identified the potential for biased results generated using VITROS VANC Reagent for the lots listed above. This can occur after the reagent packs are loaded onto the analyser and stored within the on-analyser stability date.

Some customers observed a positive drift of >2 Standard Deviation (SD) in quality control results when using VITROS TDM Performance Verifiers (Levels I, II & III).

Our records indicate that you were shipped VITROS VANC Reagent from an affected lot.

Investigation

As stated in the Instructions for Use, once a VITROS VANC Reagent Pack is loaded, the system automatically determines the appropriate on-analyser stability time. The on-analyser stability time is continuously adjusted based upon both the number of days the reagent pack is on the analyser and the number of tests remaining in the pack.

Our testing confirmed a positive drift in patient and quality control results within a reagent pack in as few as approximately 7 hours. For the affected lots, results may begin to show a drift as soon as packs are loaded onto the system.

Impact to Results

The magnitude of positive drift for the affected reagent packs is approximately 8-15% across the VANC reportable measuring range of 5.00–50.00 µg/mL (3.35–33.50 (µmol/L). Refer to page two for detailed information.

Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Required Actions

- As a result, you must immediately discontinue using and discard all remaining inventory of VITROS VANC Reagent Packs for the affected lots listed above.
  NOTE: If you do not have an alternate lot in your inventory, refer to the information on page three for instructions to use your current lot until new product arrives.
- Complete the Confirmation of Receipt and return by **March 3, 2017.** Upon receiving your Confirmation of Receipt form, Ortho will credit your account for discarded reagent packs.
- Post this notification by each VITROS System that utilizes VITROS VANC Reagent Packs or with your user documentation.
- Forward this notification if you have distributed these products outside of your facility.

Contact Information	If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Sincerely,

[redacted]

Jon Wong, QA Manager 23 Feb 2017

Questions and Answers

1. What is the impact to my results?

Our investigation determined that there are four possible scenarios depending upon the condition of an affected reagent pack:

Scenario	Calibrated: Reagent Pack Condition Results Generated: Reagent Pack Condition	Impact Observed
1	• Calibrated: Freshly loaded pack • Results: Freshly loaded pack	Drift in results (within 2 SD) for up to approximately 7 hours, followed by positively biased results. QC results outside 2 SD after 7 hours.
2	• Calibrated: Freshly loaded pack • Results: Pack on analyser > 7 hours	Positively biased results for remainder of pack. Sustained QC results outside 2SD.
3	• Calibrated: Pack on analyser > 7 hours • Results: Pack on analyser > 7 hours	QC results within 2 SD.
4	• Calibrated: Pack on analyser > 7 hours • Results: Freshly loaded pack	Negatively biased results that may be outside of 2 SD, followed by a positive drift in results for up to approximately 7 hours.

2. What is the magnitude of the bias observed during testing?

When using an affected reagent pack (calibrated using a freshly loaded pack), our data confirmed the positive drift in results occurs within the first few hours of loading a fresh pack on the analyser.

Result using a Fresh Reagent Pack (Time 0) µg/mL (µmol/L)	Approximate Bias 7 hours µg/mL (µmol/L)	Percent Bias at 7 hours	Approximate Bias 24 hours µg/mL (µmol/L)	Percent Bias at 24 hours
9.00 (6.03)	Not tested*		1.18 (0.79)	**13%**
12.61 (8.45)	1.30 (0.87)	**10%**	1.37 (0.92)	**11%**
19.17 (12.84)	2.28 (1.53)	**12%**	2.51 (1.68)	**13%**
23.44 (15.70)	2.57 (1.72)	**11%**	2.40 (1.61)	**10%**
42.50 (28.48)	Not tested*		6.43 (4.31)	**15%**
44.59 (29.88)	4.52 (3.03)	**10%**	3.69 (2.47)	**8%**

**Not tested as per test design due to limitations of the number of replicates in the same reagent pack (50 tests/pack)*

3. Does the bias continue to increase after 24 hours?

The table below shows the impact to results if an affected reagent pack is stored on the analyser for approximately 6 days as per our test design:

Result using a Fresh Reagent Pack (Time 0) µg/mL (µmol/L)	Approximate Bias on a Reagent Pack on analyser for 6 Days µg/mL (µmol/L)	Percent Bias at 6 Days

8.53 (5.72)	1.33 (0.89)	**16%**
41.38 (27.72)	5.14 (3.44)	**12%**

4. **What if I don't have an alternate lot of product in my inventory?**

   If you do not have an alternate lot in your inventory and you have an urgent need to continue testing Vancomycin, it is acceptable to use your current lot providing that you perform quality control testing with every sample batch (i.e., 1 or more patient samples).

   Ortho recommends the following:

   - Run QC fluids *prior to* and *following* each sample batch. (Use a minimum of one control fluid at the beginning and end of each sample batch)
   - Ensure QC results are within acceptable limits prior to releasing sample results.

5. **Are all lots affected?**

   Ortho testing to date determined that the drift in results only affects VITROS VANC Reagent from Lots 31-5407, 31-5474 and 31-5506.

6. **What is Ortho doing to resolve this issue?**

   We are working to determine the root cause and will implement corrective and preventative actions as appropriate. Until cause is identified, Ortho will monitor all in-date and future lots to monitor the performance throughout its expiry dating.