

Date Issued February 8, 2017

Affected Product

Name (Unique Identifier No.)	Product Codes	Affected Lot Numbers	Expiry Dates
VITROS Chemistry Products Li Slides (10758750009466/10758750004720)	1632660	3124-0108-6568	2018- 04-01
	8318925	3124-0108-6569	2018- 05-01

VITROS Chemistry Products Li Slides quantitatively measure lithium (Li) concentration in serum and plasma using VITROS 250/350/5,1 FS/4600 and 5600 Systems.

Issue

Ortho Clinical Diagnostics (Ortho) identified the potential for intermittent imprecision in results generated using the two lots of VITROS Li Slides listed above. When present, the potential imprecision does not affect random slides, but rather sequential slides within or across slide cartridges caused by a short-duration imperfection during manufacturing.

Our records indicate that you were shipped VITROS Li Slides from a potentially affected lot.

Rate of Occurrence

Our analysis determined that there is a potential for approximately 0.2% of the slides manufactured in these two lots to be affected as shown below:

Lot Number	Slides / Cartridge	Affected Slides	Maximum Number of Potentially Affected Cartridges per Lot
3124-0108-6568	18	59 out of 25,668 (0.23%)	5
3124-0108-6569	60	118 out of 68,580 (0.17%)	3

We have had no customer complaints related to this issue.

Impact to Results

If slides are affected, then the following two scenarios could occur:

- Scenario 1: If a calibration is performed using unaffected slides, and subsequent testing is performed using affected slides:
 - Results for patient or quality control samples could be biased. Internal testing confirmed the following biases using a sample with a lithium concentration of 1.32 mmol/L*:
 - Maximum positive bias observed was +0.56 mmol/L (mEq/L)
 - Maximum negative bias observed was -1.05 mmol/L (mEq/L)
- Scenario 2: If a calibration is performed using affected slides:
 - There is a high likelihood that the calibration will fail due to the monotonicity (rep-to-rep verification) performed by the system during calibration.
 - In the unlikely event that the calibration is successful, the magnitude of bias will depend on which calibrator levels were processed using affected slides.
 - If calibration is successful, imprecise results would most likely be identified by unacceptable post calibration quality control values.

***NOTE:** Slides were tested with a lithium concentration of 1.32 mmol/L (i.e., upper end of the therapeutic range). As the issue is intermittent with a low rate of occurrence, affected slides are identified and consumed during testing, therefore, this data could only be obtained at one concentration level.

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

**Required
Actions**

- As a precaution, you must immediately discontinue using and discard all remaining inventory of VITROS Li Slides, Lot 3124-0108-6568 and 3124-0108-6569.
- Complete the Confirmation of Receipt and return by **February 20, 2017**. As indicated on your Confirmation of Receipt form, Ortho will credit your account or send a replacement order for discarded slides.
- Post this notification by each VITROS System that utilizes VITROS Li Slides or with your user documentation.

**Identification
of Lot
Number**

Below is an example of how to identify the lot number on the product packaging (e.g. 3124-0108-6568):

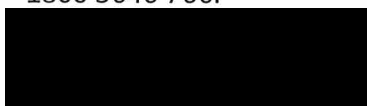
SO/GEN	Coating ID	Lot No.
3124	0108	6568

Root Cause

Ortho has determined the root cause of this issue. We have implemented corrective and preventative actions to help mitigate future occurrences.

**Contact
Information**

If you have further questions, please contact our Ortho Care™ Technical Solutions Center at 1800 5646 766.



Jon Wong
QA Manager