

May 20, 2016

URGENT PRODUCT CORRECTION NOTIFICATION

Negatively Biased Results using VITROS® Chemistry Products Ca Slides, Generation (GEN) 29

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

Product Name (Unique Device Identifier No.)	Product Code	Affected GEN	Expiry Dates
VITROS Chemistry Products Ca Slides, GEN 29 (10758750009114, 20758750009111)	1450261	GEN 29	01-Mar-2017 through 01-Jul-2017

Ortho Clinical Diagnostics (Ortho) has confirmed biased results when using VITROS Ca Slides, GEN 29. Our records indicate that you were shipped the affected product.

VITROS Ca Slides quantitatively measure calcium (Ca) concentration in serum, plasma, and urine using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and VITROS 5600 Integrated Systems.

Impact to Result

Ortho identified the potential for negatively biased serum sample results generated when using VITROS Ca Slides, GEN 29. Our testing confirmed an average negative bias of -0.45 mg/dL (-0.11 mmol/L) within the serum reference interval. Refer to page three for additional information.

NOTE: Plasma samples are similarly affected as serum samples as both sample types use the same calibration parameters (math). To date, we have no indication that urine sample results generated when using GEN 29 are affected.

Discuss any concerns you may have regarding previously reported calcium results with your Laboratory Medical Director to determine the appropriate course of action. The results from this or any other diagnostic test should be used and interpreted only within the context of the overall clinical picture.

Actions Required from You

1. Upon receipt of your replacement order, please discontinue using and discard all remaining inventory of VITROS Ca Slides, GEN 29. We will replace your remaining inventory or credit your account per your selection on the Confirmation of Receipt form.
2. Post this notification by your VITROS System or with your user documentation.
3. Complete the Confirmation of Receipt form and return within **(2) two business days** to indicate that you have been informed of this Product Correction.

We apologize for the inconvenience this will cause your laboratory. We have anticipated some questions you may have in the following Question and Answer section. If you have additional questions, please contact Customer Technical Services at **1800 5646 766**.

Yours sincerely,



Lee, Ching Hwee
Associate Manager Regulatory Affairs

Questions and Answers

1. Are all VITROS Ca Slides affected by this issue?

No, our testing confirmed that this issue only affects GEN 29 slides. As a result, upon receiving replacement product please discontinue using and discard your remaining inventory of GEN 29.

We are monitoring all other GENs to help assure that they are performing as expected.

2. How can I determine the GEN Number for the VITROS Ca Slides in my inventory?

Example Lot number (#) used to determine the GEN number on the product packaging (e.g. 0329-0528-7000):

SO/GEN #	Coating ID	Lot #
0329	0528	7000

3. What is the impact to my results?

Ortho's investigation identified that serum sample results generated using VITROS Ca Slides, GEN 29 were negatively biased compared to our reference method (Atomic Absorption) shown below:

Average Bias Observed within Reference Interval for <u>Serum</u> Samples: (8.4 – 10.2 mg/dL)	Average Bias Observed within Reference Interval for <u>Serum</u> Samples: (2.10 – 2.55 mmol/L)
-0.45 mg/dL	-0.11 mmol/L
To date, Ortho has no indication that urine sample results using GEN 29 are affected. VITROS Ca Slides uses calibration parameters (math) specifically derived for urine samples.	

4. Should I take any action on previously reported results generated using VITROS Ca Slides, GEN 29?

Discuss any concerns you may have regarding previously reported calcium results with your Laboratory Medical Director to determine the appropriate course of action. The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.

5. Will this issue be detected by quality control testing?

The negative bias is not detected when using VITROS Chemistry Products Performance Verifiers I and II as results will be within Range of Means (ROM) established for GEN 29. However, it could be detected if using another manufacturer's quality control fluids.

6. What should I do with my remaining inventory of the affected lots?

Upon receipt of your replacement order, discard all remaining inventory of VITROS Ca Slides, GEN 29. We will replace your remaining inventory or credit your account per your selection on the Confirmation of Receipt form. Partial sales units that remain can only be credited.