



December 2019

IMPORTANT PRODUCT CORRECTION NOTIFICATION**Potential for Negatively Biased Na⁺ Urine Results Using
Several Lots of VITROS® Chemistry Products Calibrator Kit 2**

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

The purpose of this notification is to inform you that Ortho Clinical Diagnostics has found that negatively biased URINE results may occur when using *specific* coatings of VITROS® Chemistry Products Na⁺ Slides with VITROS Chemistry Products Calibrator Kit 2.

Product Name (Unique Identifier No.)	Product Code	Affected Lot No.	Expiry Date
VITROS® Chemistry Products Calibrator Kit 2 (10758750009503)	1662659	Lot 277	11-Dec-2019
		Lot 288	31-May-2020
		Lot 298	12-Nov-2020
		Lot 219	15-Jul-2021

Results for Na⁺ Serum/Plasma samples are NOT affected by this issue.

Description of Issue

This product correction notification has been initiated due to the potential for negatively biased URINE sample results to occur when using specific coatings of VITROS Na⁺ Slides after calibration with the lots of VITROS Calibrator Kit 2 listed above.

Results for URINE samples obtained when some coatings of VITROS Na⁺ Slides are calibrated with the affected lots of VITROS Calibrator Kit 2 may be negatively biased and quality control fluids may be outside of the expected ranges.

The following VITROS Na⁺ Slides (Product Code 8379034) are impacted by the VITROS Calibrator Kit 2 issue:

- **GEN 19: Coatings 1018, 1019, 1022, 1023**
- **GEN 24: Coating 1020**
- **GEN 25: Coatings 1017, 1021**
- **GEN 26: Coatings 1024, 1025**

Impact to Results

The average bias observed in our investigation is described in the enclosed data sheet.

Urine Na⁺ test is mainly used to determine the cause of an abnormal blood Na⁺ level. Falsely low urine Na⁺ results may cause confusions to the physicians leading to delayed diagnosis or delayed optimal patient treatment. A review of previous urine Na⁺ results is not recommended, as normally there is no

long-term value of urine Na⁺ results for patients previously treated. Discuss any concerns regarding previously reported Na⁺ results with your Laboratory Medical Director or with the requesting physician.

REQUIRED ACTIONS

- For laboratories that do NOT process urine samples on VITROS Na⁺ Slides: **No further action is required.**
- For laboratories that process urine samples on VITROS Na⁺ Slides and calibrate with VITROS Calibrator Kit 32: **No further action is required.**
- For laboratories that process urine samples on VITROS Na⁺ Slides and calibrate with VITROS Calibrator Kit 2:
 - If you have VITROS Calibrator Kit 32, immediately recalibrate VITROS Na⁺ Slides with VITROS Calibrator Kit 32.
 - If you do not have VITROS Calibrator Kit 32, immediately place an order for VITROS Calibrator Kit 32.
 - Use an alternate urine sodium method until calibration with VITROS Calibrator Kit 32 is complete.
 - If no alternate urine sodium method is available, consult with your medical director to determine if it is acceptable for continued use until:
 - Calibration with VITROS Calibrator Kit 32 is complete.
 - VITROS Na⁺ Slides GEN 26 performance is updated (refer to Resolution section). VITROS Calibrator Kit 2 is acceptable to use after this occurs.
 - VITROS Na⁺ Slides GEN 27 or higher is available. VITROS Calibrator Kit 2 is acceptable to use after this occurs.

Note: To use VITROS Calibrator Kit 32, VITROS 250/350 Chemistry Systems must have Software Version 9.7 installed.

- Complete the Confirmation of Receipt form no later than **January 6, 2020**.
- Post this notification by each VITROS System in your facility or with the user documentation.
- Forward this notification if the product was distributed outside of your facility.

Resolution

It is possible to be shipped affected lots of VITROS Calibrator Kit 2 and/or impacted lots of VITROS Na⁺ Slides until we replenish our inventory. VITROS Na⁺ Slides, GEN 27 and above, are not impacted by this issue and are expected to be available in early January 2020.

The calibrator values for VITROS Na⁺ Slides, GEN 26 (i.e., Coatings 1024 & 1025) will be revised. We anticipate this update will be available in mid-late January 2020. The applicable Calibration Diskette/Assay Data Diskette (ADD) History Chart will identify the revision. The Liquid Performance Verifier range of means for GEN 26 will also be updated. Obtain the applicable Assay Sheet from the Ortho website after the revised Calibration Diskette/ADD is loaded.

Upon the first time loading the Calibration Diskette/ADD with the revised values, **VITROS Na⁺ Slides Gen 26 (serum and urine) will become uncalibrated and will require recalibration. This will occur for calibrations performed with both VITROS Calibrator Kit 2 or Kit 32.**

Our root cause investigation is ongoing; we will implement additional corrective actions as appropriate.

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Enclosure:

1. Impact to Results Data Sheet (Ref. CL2019-343_Impact to Results)
2. Confirmation of Receipt form (CL2019-343ea_Conf)

Questions and Answers

1. Are previously reported VITROS Na⁺ URINE results impacted?

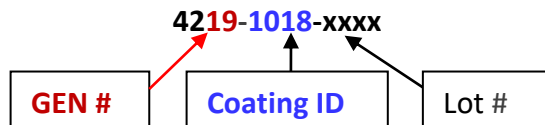
Any URINE sodium results generated using an impacted VITROS Na⁺ Slide coating when calibrated with an affected lot of VITROS Calibrator Kit 2 could be impacted. Refer to the enclosed Impact to Results summary and discuss any concerns you may have regarding previously reported URINE Na⁺ results with your Laboratory Medical Director or with the requesting physician.

2. Will this issue be detected by Quality Control testing?

This issue may not be readily detectable by processing quality control fluids. It is possible for Na⁺ quality control results to appear acceptable even though patient results are lower than expected.

3. How can I determine if the VITROS Na⁺ Slides in my inventory are impacted?

Use the example below to determine the GEN and Coating on the product packaging:



4. Does the issue affecting VITROS Calibrator Kit 2 impact any other assays that use this kit for calibration?

No, this issue only impacts the calibration of certain coatings of VITROS Na⁺ Slides. No other assays are impacted.

5. If I am currently using an impacted coating of VITROS Na⁺ Slides, can I get replacement for my remaining slide inventory?

No, use VITROS Calibrator Kit 32 to calibrate your current inventory of VITROS Na⁺ Slides.