Ortho Clinical Diagnostics	**URGENT PRODUCT CORRECTION NOTIFICATION** **Revised Reagent Preparation Instructions for VITROS® Chemistry Products Na^+ Slides**

Date December 2016

Affected Products

Product Name (Unique Device Identifier No.)	Product Code	Generation (GEN)	Expiry Dates
VITROS Chemistry Products Na^+ Slides (10758750004812)	8379034	**1 through 6** **30 through 40** **44 through 49**	01-JAN-2017 through 01-JUN-2018
NOTE: This issue affects all expired, in-date GENs (listed above) and future product until further notice.			

VITROS Na^+ Slides quantitatively measure sodium (Na+) concentration in serum, plasma, and urine using VITROS 250/350/5,1 FS/4600/5600 Systems.

Issue Description

Ortho Clinical Diagnostics (Ortho) has identified the potential for biased results to be generated within the 10 day on-analyser period when using VITROS Na+ Slide cartridges warmed between 1½ to 8 hours prior to opening and loading. Ortho has determined that cartridges require a ***minimum of 8 hours of warm up*** at room temperature to help ensure the slides have acceptable performance throughout the 10 day on-analyser storage limit.

Current Instructions

The VITROS Na^+ Slides Instructions for Use (IFU) currently states that a slide cartridge must reach room temperature, before it is unwrapped (opened) and loaded into the slide supply (*i.e., 90 minutes from the refrigerator, 120 minutes from the freezer*). This allows the slides to equilibrate to room temperature prior to loading on the VITROS System.

Investigation Summary

Ortho has obtained data showing different performance between cartridges removed from frozen storage and warmed at room temperature for 2 hours compared to 8 or more hours. Our investigation determined variations in cartridge conditions (i.e., 2 hour versus 8-24 hour warm up) may contribute to biases as shown in three scenarios:

Scenario	Cartridge Condition	Impact Observed
1	Calibration performed using a cartridge warmed for 2 hours with results generated using a cartridge warmed for 8-24 hours.	Negatively biased results up to - 3.3 mmol/L. This scenario may cause slides stored on system prior to 10 day on-analyser storage limit to be unacceptable.
2	Calibration performed using a cartridge warmed for 8-24 hours with results generated using a cartridge warmed for 2 hours.	Positively biased results up to + 3.3 mmol/L.
3	With either calibration (Scenarios 1 or 2), cartridges warmed for the minimum 2 hours and stored on the analyser can show a change in prediction over the next 6 hours.	Results can shift negatively by up to -3.3 mmol/L in this 6 hour interval.

New Instructions	Until further notice, all unopened cartridges (foil wrap not removed), frozen or refrigerated, must be equilibrated at room temperature, 18–28 °C (64–82 °F) for a minimum of **8 hours** then loaded on the VITROS System within 24 hours after removal from the refrigerator or freezer. Following these instructions will allow VITROS Na+ Slides to maintain stability over the 10 day on-analyser storage limit and may also reduce your standard deviation for QC results.
Impact to Results	If your Quality Control (QC) results were within acceptable limits, previously reported results were not affected and a retrospective review of results is not required.
Required Actions	• Until further notice, unopened VITROS Na^+ Slides cartridges must be stored at room temperature, 18–28 °C (64–82 °F) for a minimum of **8 hours** when stored frozen or refrigerated. • As soon as possible, recalibrate each VITROS System using a VITROS Na^+ Slides cartridge that has been warmed for a minimum of 8 hours. **Failure to recalibrate may cause biased results as described in Scenario 1.** • *As a precaution,* once fresh cartridges are available (after the 8-24 hour warm up) and you have successfully recalibrated each VITROS System, remove and discard all remaining VITROS Na^+ Slide cartridges currently stored on each system. **As indicated on your Confirmation of Receipt form, Ortho will credit your account for discarded cartridges and one sales unit of VITROS Chemistry Products Calibrator Kit 2.** **NOTE**: Until you are able to implement these instructions, you may continue to use VITROS Na+ Slides if QC results are acceptable. • Post this notification by your VITROS System or with your user documentation • Complete the Confirmation of Receipt form and return by **January 6, 2017.**
Final Resolution	Ortho is working to reduce the minimum cartridge warm up protocol through improvement projects already underway. We anticipate that this resolution will be available in the first half of 2017 but will vary based on regulatory requirements in your region.
Contact Information	We apologize for the inconvenience to your laboratory. We have anticipated some questions you may have in the following Question and Answer section. If you have additional questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Sincerely,

[redacted]

Jon Wong, 27 Dec 2016

Quality Manager

Enclosure: Confirmation of Receipt Form

Questions and Answers

1. What are the <u>current</u> reagent preparation instructions for VITROS Na^+ Slides?

The VITROS Na^+ Slides Instructions for Use states:

Current Reagent Preparation:
The slide cartridge must reach room temperature, 18–28 °C (64–82 °F), before it is unwrapped and loaded into the slide supply.

1. Remove the slide cartridges from storage.
2. *Warm the wrapped cartridge at room temperature for 90 minutes when taken from the refrigerator or 120 minutes from the freezer.*
3. Unwrap and load the cartridge into the slide supply.

NOTE: Load the cartridges within 24 hours after they reach room temperature, 18–28 °C (64–82 °F).

New Reagent Preparation:
Warm the wrapped cartridge at room temperature for a minimum of **8 hours when taken from the refrigerator or the freezer**. Cartridges must be loaded on the VITROS System within 24 hours.

2. Is there any change for other materials used to process VITROS Na+ Slides?

This change only affects the warm up time to allow the slides to equilibrate. All other materials (i.e., Calibrator Kit, Performance Verifiers, Electrolyte Reference Fluids, etc.) are not affected.

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

If present, the bias would be detected in your Quality Control results. If your quality control results were within acceptable limits, previously reported results were not affected.

4. How can I identify the GEN for the VITROS Na^+ Slides in my inventory?

Below is an *example* to identify the GEN number on the product (e.g. **4244-XXXX-YYYY**):

SO/**GEN #**	Coating ID	Lot #
4244	**XXXX**	**YYYY**