

Ortho Clinical Diagnostics	<p>URGENT FIELD SAFETY NOTICE</p> <p>Revised Reagent Preparation Instructions for VITROS® Chemistry Products Na⁺ Slides</p>
----------------------------	--

Date **December xx, 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 As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics (Ortho) initiated this Urgent Field Safety Notice having been made aware of the potential for biased results to be generated over the 10 day on-analyzer limit when using VITROS Na⁺ Slide cartridges warmed between 1½ to 8 hours then placed on the analyzer. 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-analyzer storage limit.

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

Investigation Summary Ortho 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 the 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-analyzer 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 analyzer 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	<p>Until further notice, unopened cartridges (foil wrap not removed) must be stored at room temperature, 18–28 °C (64–82 °F) for a minimum of 8 hours regardless of whether cartridges are stored frozen or refrigerated, then loaded on the VITROS System within 24 hours after they are removed from the refrigerator or freezer.</p> <p>Following these instructions will allow VITROS Na+ Slides to maintain stability over the 10 day on-analyzer storage limit and may also reduce your standard deviation for QC results.</p>
Impact to Results	<p>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.</p>
Required Actions	<ul style="list-style-type: none">• 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.• <i>As a precaution</i>, 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 or send a replacement order for discarded cartridges and one sales unit of VITROS Chemistry Products Calibrator Kit 2. <p>NOTE: Until you are able to implement these instructions, you may continue to use VITROS Na+ Slides if QC results are acceptable.</p> <ul style="list-style-type: none">• Post this notification by your VITROS System or with your user documentation• Complete the Confirmation of Receipt form and return by January x, 2017.
Final Resolution	<p>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.</p>
Contact Information	<p>We apologize for the inconvenience to your laboratory. We have anticipated some questions you may have in the following Question and Answer section. For additional questions, contact our Ortho Care™ Technical Solutions Center at insert number.</p> <p>Insert signatory if appropriate in your region</p>

Enclosure: Confirmation of Receipt Form

Questions and Answers

1. What are the current 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

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

Ortho Clinical Diagnostics

Revised Reagent Preparation Instructions for VITROS® Chemistry Products Na⁺ Slides

Please return completed form by fax or scan to PDF and email so that we can complete our records no later than: **DD-MM-YYYY**

Send to: **Name**

e-Mail Address: **email address**

Fax: **Fax Number**

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2016-226_EU) regarding reagent preparation instructions that are changed in order for VITROS Na⁺ Slides to equilibrate. I understand that I must warm all unopened VITROS Na⁺ Slide cartridges at room temperature for a minimum of 8 hours when taken from the refrigerator or the freezer.

Please choose from the following:

- My laboratory does not currently use VITROS Na⁺ Slides and is not affected by this issue.
- My laboratory uses VITROS Na⁺ Slides. As a precaution, I removed and discarded all VITROS Na⁺ Slide cartridges currently stored on my VITROS System(s). I discarded the quantity listed in the table below.

Please indicate your choice of credit or replacement:

- Credit my account (Credit can be issued for full or partial sales units.)
- Send a replacement order to the address listed below. (We can ship full sales units only.)

Product Name/Product Code/LOT	Indicate Both GEN No. /Quantity Discarded
VITROS Na ⁺ Slides	
VITROS Na ⁺ Slides	
VITROS Na ⁺ Slides	
VITROS Na ⁺ Slides	
VITROS Calibrator Kit 2*	

One Sales Unit for VITROS Na⁺ Slides = 5 Pack containing 250 Slides (Product Code 8379034)
***NOTE: Ortho will also credit or send one box of VITROS Calibrator Kit 2 to recalibrate.**

Your signature provides confirmation that you have received and understand this notification.

Your Name: _____

Phone Number: _____ Date: _____

Your Comments: _____

Signature:
Required if sent by
fax or a scanned PDF

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/

Contact Name: _____

Address: _____

City: _____ State/Prov: _____ Zip/Postal Code: _____

Phone: _____ Fax: _____

e-Mail: _____