

Ortho Clinical Diagnostics	FURTHER CORRECTIVE ACTION NOTIFICATION Reformulated VITROS® Electrolyte Reference Fluid (ERF) to Restore Reagent Preparation Instructions for VITROS® Chemistry Products Na⁺ Slides
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Date	Aug 2017
Topic	In 2016, Ortho Clinical Diagnostics (Ortho) issued a notification (Ref. CL2016-226) regarding the potential for biased results to be generated within the 10 day on-analyser storage limit using VITROS Na ⁺ Slide cartridges warmed between 1½ to 8 hours. We informed you that we were working to restore the minimum cartridge warm up protocol to previously specified limits through improvement projects.
Interim Instructions	In 2016, to minimize the potential for biased VITROS Na ⁺ results, Ortho advised that unopened cartridges must be equilibrated to 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.
Resolution	<p>Ortho is introducing VITROS Electrolyte Reference Fluid (ERF) 300 and VITROS Electrolyte Reference Fluid (ERF) 800 with a <i>revised formulation</i> that:</p> <ul style="list-style-type: none"> • Restores the Na⁺ cartridge warm-up protocol to 90 minutes when taken from the refrigerator (120 minutes from the freezer) as defined in the VITROS Na⁺ Slides Instructions for Use. • Reformulated ERF helps to reduce sources of variability (e.g., calibration variability) observed when using VITROS Na⁺ Slides. <p>IMPORTANT REMINDER: <i>If not using VITROS Electrolyte Reference Fluids 300 and 800, unopened cartridges of VITROS Na⁺ Slides must be warmed at room temperature for a minimum of 8 hours regardless of whether cartridges are stored frozen or refrigerated.</i></p>
Impact to Results	<p>When changing over to either of the reformulated ERF products, <u>there is a potential for an average shift of 0.5 mmol/L in results (positive or negative)</u>, depending on the specific GEN of VITROS Na⁺ Slides, lot of Calibrator Kit and type of ERF currently in use. The shift in results observed is within our release specifications and overall process capability.</p> <p>For VITROS K⁺ Slides or VITROS CL⁻ Slides, there is no shift in results expected using VITROS ERF 300 and VITROS ERF 800.</p>

Reformulated Electrolyte Reference Fluids (ERF).

The reformulated ERF will replace the current ERF as described below:

Reformulated Electrolyte Reference Fluids	Current Product (To be Discontinued)	For Use with these VITROS Systems
VITROS Chemistry Products Electrolyte Reference Fluid (ERF) 300 (NEW Product Code: 6844464)	VITROS Chemistry Products 250/350 Reference Fluid (ERF) (Product Code: 1765304)	VITROS <u>250 and 350</u> Chemistry Systems
VITROS Chemistry Products Electrolyte Reference Fluid (ERF) 800 (NEW Product Code: 6844463)	VITROS Chemistry Products 950/FS Reference Fluid (ERF) (Product Code: 8057812)	VITROS <u>5,1 FS, 4600 and 5600</u> Systems

VITROS Electrolyte Reference Fluid (ERF) 300 and VITROS Electrolyte Reference Fluid (ERF) 800 is used for the potentiometric measurement of sodium (Na⁺), potassium (K⁺), and chloride (Cl⁻).

The storage and stability claims have not changed. The product names reflect the number of tests you can expect from each electrolyte reference fluid reservoir (same as the current ERF).

- VITROS Electrolyte Reference Fluid (ERF) 300 will yield 300 tests per reservoir.
- VITROS Electrolyte Reference Fluid (ERF) 800 will yield 800 tests per reservoir.

Ordering Information

VITROS ERF 300 and VITROS ERF 800 reference fluids have NEW product codes (listed above); notify your purchasing department of this change that will appear on the invoice. Product pricing will remain the same.

To place an order, contact our Customer Service representatives at 1800 5646766. We anticipate that the reformulated ERF will begin shipping in a few weeks. In-process orders of VITROS 250/350 Reference Fluid and VITROS 950/FS Reference Fluid may be fulfilled by VITROS ERF 300 and VITROS ERF 800, respectively.

Using Reformulated ERF

We recommend that you finish your current inventory of VITROS 250/350 and 950/FS Reference Fluids, PRIOR to using the reformulated VITROS Electrolyte Reference Fluid (ERF) 300 and VITROS Electrolyte Reference Fluid (ERF) 800.

As per the Instructions For Use (IFU), (re)calibrate VITROS Na⁺, K⁺, and Cl⁻ Slides with every ERF lot change.

Obtaining IFUs

VITROS Electrolyte Reference Fluid (ERF) 300 and VITROS Electrolyte Reference Fluid (ERF) 800 IFUs are available on our website at <http://www.orthoclinical.com>.

Contact Information

If you have any questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Sincerely,



Jon Wong, QA Manager

Enclosure: Confirmation of Receipt form