



July 16, 2018

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Revisions to VITROS® Chemistry Products Cl⁻ Slides & VITROS® Chemistry Products CREA Slides

Dear Customer,

This notification provides information regarding revisions to the products listed below.

Product	Product Code (Unique Device Identifier No.)	Affected Generations (GENs)
VITROS® Chemistry Products Cl ⁻ Slides	6844471 (GEN 10 & Above) (10758750031658)	These corrections are being applied to all expired, in-date and future GENs released.
	8445207 (GEN 5 & Below) (10758750004928)	
VITROS® Chemistry Products CREA Slides	6802584 (10758750002849)	

VITROS Chemistry Products Cl⁻ Slides quantitatively measure chloride (Cl⁻) concentration in serum, plasma and urine.
 VITROS Chemistry Products CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma and urine.
 Both assays can be processed using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and VITROS 5600 Integrated Systems.

Revisions to VITROS Cl⁻ Slides

Ortho Clinical Diagnostics (Ortho) performed internal testing and determined that the current information in the VITROS Cl⁻ Slides Instructions for Use (IFU) needs to be revised as follows:

Product	Current Specificity	Revised Specificity
VITROS Cl ⁻ Slides (Serum/Plasma)	Triglyceride at 800 mg/dL does not interfere.	<i>6.78 mmol/L</i> Triglyceride at 600 mg/dL may cause a positive bias of approximately 2.1 mmol/L.
Product	Current Limit of Quantitation (LoQ)	Revised Limit of Quantitation (LoQ)*
VITROS Cl ⁻ Slides (Urine)	LoQ = 5 mmol/L	LoQ = 15 mmol/L

*The Limit of Quantitation (LoQ) is being revised to 15 mmol/L as determined by the lowest concentration at which precision design requirements were met within the linear range of the assay.

Impact to Cl⁻ Results

The chloride assay is often used as part of electrolyte or basic metabolic panels to identify electrolyte imbalance. It may also be used to calculate anion gap (AGP or AGPK). **A positive bias of this magnitude due to triglyceride interference may not detect minor to moderate hypochloremia and a calculated anion gap will be erroneously low.**

Continue to follow your Standard Operating Procedure for the review and release of results for any impact of endogenous or exogenous interferences including high triglyceride on Chloride results. Discuss any concerns you may have regarding results with your Laboratory Director to determine 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.

Ortho has not received any customer complaints related to this issue.

Revisions to VITROS CREA Slides

Ortho performed internal testing and determined that the current Measuring (Reportable or Dynamic) Range for VITROS CREA Slides needs to be revised as follows:

Product Name	Current Measuring Range for Serum	Revised Measuring Range for Serum
VITROS CREA Slides (Serum)	0.05 – 14.0 mg/dL	0.15 – 14.0 mg/dL
	4-1238 µmol/L	13-1238 µmol/L
	0.5 – 140 mg/L	1.5 – 140 mg/L
	Current Measuring Range for Urine	Revised Measuring Range for Urine
VITROS CREA Slides (Urine)	1.2 – 346.5 mg/dL	3.2 – 346.5 mg/dL
	106 – 30631 µmol/L	283 – 30631 µmol/L
	12.0 – 3465 mg/L	32.0 – 3465 mg/L

(0.013)

(0.283)
We report mmol/L.

These revisions are applicable to the IFU and VITROS Systems that process the slides. Ortho has not received any customer complaints related to this issue.

Impact to Laboratory Information System (LIS), VITROS Automation Solutions or enGen™ Laboratory Automation Systems:

- If you have written custom rules that involve the Measuring Range for Creatinine, review the rules to determine if an update is needed.
- If you have rules for reordering tests based on the results at or below the low end of the Measuring range for Creatinine, review the rule to determine if an update is needed to your LIS.
- If the Measuring Range is defined in the LIS or Laboratory Automation System, it needs to be assessed.

Resolution

VITROS Cl⁻ Slides and VITROS CREA Slides Instructions for Use will be updated to contain the revised information described in this letter¹; we will notify you upon availability. In the interim, retain a copy of this customer letter for your records.

Calibration Diskette and ADD Data Release Version (DRV) 5992 (and above) will support the revised measuring range for VITROS CREA Slides. We anticipate that DRV 5992 will be available the week of July 28, 2018 by eConnectivity or will be sent via your normal Cal Disk or ADD mailing schedule.

REQUIRED ACTIONS when using VITROS Cl⁻ Slides

- Prior to the availability of the revised IFU, be aware that if a serum or plasma sample contains a Triglyceride concentration of 600 mg/dL or higher, the Chloride result may be positively biased by approximately 2.1 mmol/L. Follow your normal laboratory procedures as you would for other known assay interferences. **Note:** It is acceptable to continue using VITROS Cl⁻ Slides.

REQUIRED ACTIONS when using VITROS CREA Slides

- Upon availability, install the Calibration Diskette or ADD to implement the revised Measuring Range:

¹ Revised IFUs will be available in approximately 4 – 6 weeks.

- **For VITROS 4600, 5600 or 5,1 FS Systems:** Install ADD DRV 5992 or above, Select “All Assay Data” option
- **For VITROS 250/350 Systems:** Install Calibration Diskette DRV 5992 or above
- Refer to the enclosure for additional instructions to update the Measuring Range (either with the Calibration Diskette or ADD, or manually).
- Update laboratory procedures and your Laboratory Information System (LIS), as necessary.

REQUIRED ACTIONS for both slides

- Retain this letter until we send a notification to alert you when the revised IFUs are available.
- Complete the Confirmation of Receipt form and return by **July 30, 2018**.
- Post this notification by each system that processes VITROS CI⁻ or CREA Slides.
- Forward this notification if the product was distributed outside of your facility.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care™ Technical Solutions Center at 1-800-421-3311.

Enclosure: Instructions to Revise the Measuring Range for VITROS CREA Slides on VITROS Systems

