IMPORTANT

Ortho Clinical Diagnostics

July 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 Instructions for Use (IFU) for the products listed below.

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

Revisions to VITROS Cl^- Slides

Ortho Clinical Diagnostics (Ortho) has determined that the 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 **9 mmol/L** does not interfere.	Triglyceride at **6.8 mmol/L** 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 has 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

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.

IMPORTANT TO NOTE: These revisions have not been cleared or approved in your region. Therefore, you may wish to manually update the Measuring Range back to the current values every time an ADD or Calibration Diskette is installed.

Resolution

VITROS Cl^- Slides and VITROS CREA Slides Instructions for Use will be updated to contain the revised information described in this letter; 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 beginning on July 28, 2018 by eConnectivity or will be sent via your normal Cal Disk or ADD mailing.

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 6.8 mmol/L (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

- Until the revised IFU is available in your region, you may wish to manually update the Measuring Range to revert back to the current values or use the new values using the appropriate set of instructions provided.
- After installing Calibration Diskette or ADD DRV 5992 or above, follow the enclosed procedure until further notice.

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 23, 2018.**
- Post this notification by each system that processes VITROS Cl^- 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 your local Ortho representative or our Ortho Care™ Technical Solutions Centre at *1800-5646-766*

Sincerely,

[redacted]

Jon Wong

QA Manager

Enclosures:

1. Instructions to manually update to Current Measuring Range Values on VITROS Systems
2. Instructions to update to the New Measuring Range for VITROS CREA Slides on VITROS Systems

Instructions to Manually Update to Current Measuring Range Values on VITROS Systems

To update the Reportable Range for VITROS CREA Slides on VITROS 4600, 5600 or 5,1 FS Systems:

- Upon installation of ADD DRV 5992 the Measuring Range will be updated on your system if it is loaded using *'Restore Defaults'*

- **To manually update the Measuring Range to current values for CREA:**

  - From the main menu Select *Options*
  - Select *Review/Edit Calibrations*
  - Select *fluid type*
  - Select *Serum or Urine*
  - Select *Review Assay Data*
  - Select the appropriate *GEN #*
  - Touch the box that displays the low end of the *Measuring (Reportable) Range'*
  - Using the keyboard Select *Delete*
  - Using the keyboard, enter the **0.05** for the serum value or **1.2** for the urine value
  - Select *Save*
  - Select *Yes*
  - Repeat for both serum and urine and for each GEN on your system

  Note: The User Modified center box will then display 'M1'

  To make a back up diskette to save these changes:

  - From the main menu, select *Options*
  - Select *Perform Backup*
  - Select *Full Backup* (follow the screen prompts)

- If you loaded ADD 5992 utilizing the *'Retain Modified'* –your Measuring Range remains unchanged. You must verify that the ranges were NOT updated.

If using *'Retain Configuration'*, confirm that the Measuring Range for CREA was not revised:

- From the main menu Select *Options*
- Select *Review/Edit Calibrations*
- Select *Serum, Plasma or Urine*
- Select *CREA*
- Select *Review Assay Data*
- Select the *GEN #*
- Repeat for each GEN and Body Fluid utilized on your system

REQUIRED ACTIONS for VITROS 250/350 Systems:

- Upon installation of ADD DRV 5992 the Measuring Range will be updated on the system if it is loaded using *'Restore Defaults'*

- **To manually update the Measuring Range to current values for CREA:**

  - From the main menu Select *OPTIONS*
  - Select *COEF & LIMITS*
  - Select *TEST DATA*
  - Select *SERUM or URINE*
  - Select *CREA*
  - Hit the *enter* to move the cursor to the 'Dynamic Range'
  - Using the keyboard, type over the current value, enter the **0.05** for the serum value or **1.2** for the urine value. Do the same for the 'Analyzer Range' Low field.
  - Repeat for each GEN and body fluid on your system

  Note: The User Modified center box will then display 'M1'

  To make a back-up diskette to save these changes:

  - From the main menu, select *OPTIONS*
  - Select *BACKUP/RESTORE DISKETTE*
  - Select *BACKUP QC/CONFIG CAL DATA* (follow the screen prompts)

- If you loaded ADD 5992 utilizing the *'Retain Modified'* –your Measuring range remains unchanged. You must verify that the ranges were NOT updated.

If using *'Retain Configuration'* confirm that the Dynamic Range for CREA was not revised:

- From the main menu Select *OPTIONS*
- Select *COEF & LIMITS*
- Select *TEST DATA*
- Select *SERUM or URINE*
- Select *CREA*
- Confirm that the Dynamic Range for CREA was revised
- Select *Display GEN* at the bottom right of the screen
- Repeat for each GEN and body fluid on your system

To update the Reportable Range for VITROS CREA Slides on VITROS 4600, 5600 or 5,1 FS Systems:

- Upon availability, install ADD DRV 5992 to implement the revised Measuring Range.
- Select the "*All Assay Data*" option, an Assay Configuration dialog box will prompt you to select either *'Restore Defaults'* (**Option 1**) or *'Retain Configuration'* (**Option 2**).
- Choose the appropriate option based upon if your system contains user –modified parameters that are flagged with an "M1" code.

IMPORTANT TO NOTE: If you configured reflex dilutions, reflex reductions or made Measuring Range changes to any assay, use the *'Retain Configuration'* (**Option 2**) to save your configuration changes.

	Restore Defaults (Option 1)	Retain Configuration (Option 2)
1. Determine if any assays are user-modified on your system(s)	Follow directions for option 1 if CREA or *other* assays have not been previously user-modified.	Follow directions for option 2 if CREA or *other* assays have been user-modified.
2. Select the appropriate option when loading DRV 5992	Load DRV 5992, select *'Restore Defaults'* when prompted by the Assay Configuration dialog box.	Load DRV 5992, select *'Retain Configuration'* when prompted by the Assay Configuration dialog box.
3. Actions Required	Reportable range for CREA will be revised upon the loading of the DRV 5992. No further action is required.	Verify that the reportable range for CREA has been revised, if not, you will need to *manually* enter the decreased reportable range following the directions below.

If using *'Retain Configuration'* (Option 2), confirm that the Measuring Range for CREA was revised:

- From the main menu Select *Options*
- Select *Review/Edit Calibrations*
- Select *Serum, Plasma or Urine*
- Select *CREA*
- Select *Review Assay Data*
- Select the *GEN #*
- Repeat for each GEN and Body Fluid utilized on your system

If the Measuring Range for CREA was not automatically revised (Option 2), manually enter as follows:

- From the main menu Select *Options*
- Select *Review/Edit Calibrations*
- Select *fluid type*
- Select *Serum or Urine*
- Select *Review Assay Data*
- Select the appropriate *GEN #*
- Touch the box that displays the low end of the *Measuring (Reportable) Range'*
- Using the keyboard Select *Delete*
- Using the keyboard, enter the revised value located in the customer letter
- Select *Save*
- Select *Yes*
- Repeat for both serum and urine and for each GEN on your system

Note: The User Modified center box will then display 'M1'

To make a back up diskette to save these changes:

- From the main menu, select *Options*
- Select *Perform Backup*
- Select *Full Backup* (follow the screen prompts)

REQUIRED ACTIONS for VITROS 250/350 Systems:

- Upon availability, install the Calibration Diskette DRV 5992 to implement the revised Measuring Range. An Assay Configuration dialog box will prompt you to select either *'Load Default Values'* (**Option 1**) or *'Retain Modified Values'* (**Option 2**).
- Choose the appropriate option based upon if your system contains user –modified parameters that are flagged with an "M1" code.

IMPORTANT TO NOTE: If you configured reflex dilutions, reflex reductions or made Measuring Range changes to any assay, use the *'Retain Configuration'* (**Option 2**) to save your configuration changes.

	Load Default Values (Option 1)	**Retain Modified Values (Option 2)**
1. Determine if any assays are user-modified on your system(s)	Follow directions for option 1 if CREA or *other* assays have not been previously user-modified.	Follow directions for option 2 if CREA or *other* assays have been user-modified.
2. Select the appropriate option when loading DRV 5992	Load DRV 5992, select *'Load Default Values'* when prompted by the Assay Configuration dialog box.	Load DRV 5992, select *'Retain Modified Values'* when prompted by the Assay Configuration dialog box.
3. Actions Required	Reportable range for CREA will be revised upon the loading of the DRV 5992. No further action is required.	Verify that the reportable range for CREA has been revised, if not, you will need to *manually* enter the decreased reportable range following the directions below.

If using *'Retain Configuration'* (Option 2), confirm that the Dynamic Range for CREA was revised:

- From the main menu Select *OPTIONS*
- Select *COEF & LIMITS*
- Select *TEST DATA*
- Select *SERUM or URINE*
- Select *CREA*
- Confirm that the Dynamic Range for CREA was revised
- Select *Display GEN* at the bottom right of the screen
- Repeat for each GEN and body fluid on your system

If the Measuring Range for CREA was not automatically revised (Option 2), manually enter as follows:

- From the main menu Select *OPTIONS*
- Select *COEF & LIMITS*
- Select *TEST DATA*
- Select *SERUM or URINE*
- Select *CREA*
- Hit the *enter* to move the cursor to the 'Dynamic Range'
- Using the keyboard, type over the current value; enter the revised value located in the customer letter. Do the same for the 'Analyzer Range' Low field
- Repeat for each GEN and body fluid on your system

Note: The User Modified center box will then display 'M1'

To make a back-up diskette to save these changes:

- From the main menu, select *OPTIONS*
- Select *BACKUP/RESTORE DISKETTE*
- Select *BACKUP QC/CONFIG CAL DATA* (follow the screen prompts)

Confirmation of Receipt – Response Required

Communication ID: CL2018-148 Date of Issue: 2018-July

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Revisions to VITROS® Chemistry Products Cl^- Slides & VITROS® Chemistry Products CREA Slides

*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **23-JULY-2018**

Send to: Anthony Leung e-Mail Address: [redacted] Fax: 64861186

Your Name and Address

Please complete this section

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____

Please Confirm

I received the Important Product Correction Notification regarding the following revisions:

- **For VITROS Cl^- Slides**: The triglyceride is now identified as an interferent at a concentration of 6.8 mmol/L (600 mg/dL) when processing serum/plasma samples and the LoQ is revised from 5 to 15 mmol/L when processing urine samples.
- **For VITROS CREA Slides**: The current Measuring Range for serum/plasma and urine was revised. I will follow the instructions provided in this notification to implement the revised Measuring Range on my VITROS System(s).

Your Name: _____
Phone Number: _____ Date: _____

Signature:
Required if sent by fax or a scanned PDF

Your Comments: _____