Ortho Clinical Diagnostics

September x, 2014

URGENT FIELD SAFETY NOTICE

Anomaly Using Software Version 3.0 & Below on VITROS® 4600 Chemistry Systems & VITROS® 5600 Integrated Systems

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this communication is to inform you that Ortho Clinical Diagnostics (OCD) has identified an anomaly with VITROS® System Software Version 3.0 and below. Internal testing confirmed that when using calibrator barcode labels supplied with VITROS® Chemistry Products Calibrator Kits 1, 2, 3, 4, 6, or 9, an unexpected assay calibration may occur if assay targets are unassigned (i.e., hidden). The following System Software is affected:

VITROS® System	System Product Code	Affected VITROS® Software Version
VITROS® 4600 Chemistry System	6802445	Version 3.0 & Below
VITROS® 5600 Integrated System	6802413	

Background Information

Beginning in March 2009, calibrator barcode labels were included with VITROS® Chemistry Products Calibrator Kits 1-10 and 25. These labels are only intended for use with VITROS® 4600 and VITROS® 5600 Systems. There are two ways to perform a calibration on your VITROS® System: manually programming the calibration by selecting the appropriate assay targets, or using the barcode labels provided with the calibrator kits listed above.

Description of Anomaly

Our internal investigation confirmed that under specific circumstances (described on page 3), unexpected assay calibrations may occur if ALL of the following conditions are met:

- Using calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9.
- The VITROS® System is configured with an unassigned target for assays for one or more body fluid types supported by VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9.
- An unassigned assay target has an expired or failed calibration.

IMPORTANT TO NOTE: This issue will **NOT** occur if you manually program by selecting the assay targets during calibration programming, and do not use the barcode labels provided with the calibrators.

Required Actions

- Do not use the calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9 until the next version of software is installed on your VITROS® System.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- Post this notification by each VITROS® System in your facility or with the user documentation.
- Complete and return the Confirmation of Receipt form no later than **September xx, 2014**.
- Please contact Ortho Clinical Diagnostics if you become aware of an impact to patient safety caused by this anomaly.

Impact to Results

If an unexpected calibration occurs for an assay and is not detected by the operator, quality control may not have been processed to verify the validity of the calibration. However, quality control fluids would be performed at the next routinely scheduled time period. If quality control results were acceptable, patient results would not have been adversely affected.

If an unexpected calibration had occurred and was not detected by the operator, biased results may not have been detected. Due to the various scenarios that may lead to a sub-optimal calibration, OCD is unable to provide an estimate of the potential bias as the magnitude would be dependent upon your system and the circumstances pertaining within your facility at the time of the calibration event. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Resolution

The resolution to this software anomaly is contained the next version of software that is scheduled to be released in the near future. Until the new software is installed on your VITROS® System, do not use the calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9. We advise that you manually program the calibration.

We apologize for the inconvenience this may cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number*.

Sincerely,

insert appropriate name
insert appropriate title

Enclosures:

- Confirmation of Receipt Form
- List of VITROS® MicroSlide Calibrator Kits

Questions and Answers

1. What specific sequence of events causes the anomaly to occur?

For unexpected calibrations to transpire, the following scenario is an example of how this issue may occur.

A. The assay target for PHOS (Urine only) was unassigned (i.e., hidden) (Refer to Question and Answer # 3).

B. A new lot of VITROS® Glucose Slides is loaded on the system.

C. A calibration is performed using VITROS® Calibrator Kit 1 which also supports VITROS® PHOS Slides. Calibrator fluids were transferred into VITROS® Micro Sample Cups and the barcode labels from the kit were affixed to each tube.

D. The tray of calibrator fluids was placed in the Load position of the routine lane or STAT lane and sampling was initiated. Calibration occurred based upon the "Bar-coded Rules" previously selected for the system. (Refer to Question and Answer # 2).

E. VITROS® Glucose Slides (Serum/Urine/CSF) were calibrated as intended.

F. VITROS® PHOS Slides (Serum) were unexpectedly calibrated.

G. The assay target for VITROS® PHOS Slides (Urine only) was unassigned; the calibration for the unassigned target failed or expired. Based upon the Bar-Coded Calibrator Rules, VITROS® PHOS Slides were also calibrated even though the serum calibration was within date.
IMPORTANT TO NOTE: If an operator was unaware that VITROS® PHOS Slides were calibrated, laboratory procedures to verify the validity of the new/unexpected calibration may not have been performed.

2. What are Bar-Coded Calibrator Rules when using barcode labels for calibration?

Rules are selected by the operator during setup using the following menu options:

Options > Configure System> Calibrator rules

The following rules may be selected:

- ✓ New Lot or Lot Uncalibrated by ADD load
- ✓ Calibration With a Current/Failed Status
- ✓ Current Calibration That Will Expire in:
  (xx) Days for MicroSlide Assays
  NOTE: This rule will include calibrations that have already expired.

3. What is an unassigned assay target?

An unassigned assay target is a target that was not assigned to a screen position for a body fluid in the Options & Configuration menu:

Options & Configuration -> Configure System -> Assay Menu

Unassigning a target will remove the assay from the Sample Programming assay selection menu for that body fluid. For example, if an operator processes Serum and Plasma samples for PHOS on the VITROS® System, but does not process Urine samples, unassigning the PHOS target for Urine should prevent PHOS from inadvertently being programmed.

4. Will this anomaly occur during every calibration?

This will only occur if your system meets all of the following criteria:

- Use of calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9.
- Your VITROS® System is configured with an unassigned (hidden) target for assays for one or more body fluid types supported by VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9.
  ***NOTE:** VITROS® Calibrator Kits 7, 8, 10 & 25 only support a single assay per kit, VITROS® Calibrator Kit 5 only supports a single body fluid per assay; therefore these kits are not affected by this anomaly.
- An unassigned assay target has an expired or failed calibration.

5. What VITROS® Systems are affected by this anomaly?

This anomaly only affects VITROS® 4600 and/or 5600 Systems. Barcode labels for calibrators are only intended for use with these specific systems, which have software that will identify the calibrator kit, level, and lot number when used on sample tubes for calibration.

The potential for the anomaly to occur exists in all VITROS® 4600 and/or 5600 Software Versions 3.0 and below. No other VITROS® Systems are affected.

6. When will this anomaly be resolved?

The resolution to this software anomaly is contained in the next version of software that is scheduled to be released in the near future. Until the new software is installed on your VITROS® System, do not use the calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9. We advise that you manually program the calibration.

7. What if my VITROS® System is configured with an enGen™ Laboratory Automation System?

Since calibration is programmed and performed on the VITROS® System, the anomaly does not affect the enGen™ Laboratory Automation System.

Ortho Clinical Diagnostics

URGENT PRODUCT CORRECTION NOTIFICATION

Anomaly Using Software Version 3.0 & Below on
VITROS® 4600 Chemistry Systems & VITROS® 5600 Integrated Systems

An unexpected assay calibration may occur when using calibrator barcode labels supplied with VITROS® Chemistry Products Calibrator Kits for assay targets that are unassigned. As a result, do not use the calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9 until the next version of software is installed on your VITROS® System.

VITROS® MicroSlide Calibrator Kits		
Product Name	**Related Tests**	
Calibrator Kit 1	• BUN/UREA • Ca • CREA • GLU • LAC • Li	• Mg • PHOS • SALI • THEO • URIC
Calibrator Kit 2	• Na^+ • K^+ • CL^-	• ECO_2 • CHOL • TRIG
Calibrator Kit 3	• AcP • ALT • ALKP • AMYL • LIPA	• AST • CK • GGT • LDH
Calibrator Kit 4	• ALB • TP • Bu • Bc	• TBIL • Fe • TIBC
Calibrator Kit 5	• AMON	• PROT
Calibrator Kit 6	• CHE	• CKMB
Calibrator Kit 7	• CRP	
Calibrator Kit 8	• ALC	
Calibrator Kit 9	• ACET • CRBM • DGXN	• PHBR • PHYT
Calibrator Kit 10	• UPRO	
Calibrator Kit 25	• dHDL	
NOTE: VITROS® Calibrator Kits 5, 7, 8, 10 & 25 are <u>not</u> affected by this anomaly.		

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

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Anomaly Using Software Version 3.0 & Below on VITROS® 4600 Chemistry Systems & VITROS® 5600 Integrated Systems

Please return completed form by fax or scan to PDF and email so that we can complete our records no later than: xx-Sept-2014

Send to: Name e-Mail Address: email address Fax: Fax Number

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2014-232_EU) regarding an unexpected assay calibration when using calibrator barcode labels supplied with VITROS® Chemistry Products Calibrator Kits 1, 2, 3, 4, 6, or 9 for assay targets that are unassigned.
As a result, I am advised to not use the calibrator barcode labels for VITROS® Calibrator Kits 1, 2, 3, 4, 6, or 9 until the next version of software is installed on my VITROS® System.

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

Your Name: _____ Signature: _____
Required if sent by fax or a scanned PDF

Phone Number: _____ Date: _____

Your Comments: _____

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: _____