URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

Potential Shift in VITROS® MicroSlide Assay Results Following a System Shutdown on VITROS® XT 3400 Chemistry Systems and VITROS® XT 7600 Integrated Systems

Dear Valued Customer,

This notification provides information regarding a shift in results that has been observed after performing a system shutdown on the VITROS XT 3400 Chemistry System and VITROS XT 7600 Integrated System.

Name	Product Code (Unique Device Identifier)	Affected Software Versions
VITROS® XT 3400 Chemistry System	**6844458** (10758750031986)	**Version 3.7.2 and below**
VITROS® XT 7600 Integrated System	**6844461** (10758750031610)	

Issue Summary

Ortho Clinical Diagnostics (Ortho) became aware of an anomaly that affects VITROS XT 3400 and VITROS XT 7600 Systems. These systems utilize a Digital Imaging Reflectometer and LED light source to generate VITROS MicroSlide Assay results.

Ortho's on-going investigation has determined that performing a system shutdown on VITROS XT 3400 and VITROS XT 7600 Systems may, in some instances, cause a positive or negative shift in the electrical current supplied to the LED used in conjunction with the Digital Imaging Reflectometer. This shift in electrical current may also lead to a shift in multiple VITROS MicroSlide assay results reported by the system.

Impact to Results

Following a system shutdown, the potential exists for either a positive **or** negative shift in results reported by the VITROS System. This shift can be identified by performing routine Quality Control processing.

Refer to the 'Questions and Answers' section for a list of impacted VITROS MicroSlide assays.

A review of previously reported results is not recommended as performing routine Quality Control processing would have identified the issue. The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms as well as the results of other tests. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

REQUIRED ACTIONS

- If your VITROS XT 3400 and/or VITROS XT 7600 Systems require a system shutdown, routine Quality Control processing for MicroSlide assays must be performed per your laboratory procedure, prior to processing patient samples, to determine if the anomaly has occurred.

REQUIRED ACTIONS (CONTINUED)

- If QC results are outside your established ranges, Ortho recommends performing a second system shutdown and re-processing QC fluids for those assays that were outside your established ranges. If QC results are still outside established ranges following a second system shutdown, contact Ortho Care™ Technical Solutions Center for guidance.
- Ortho recommends using the same vial of QC fluids (*where possible*) throughout these steps to determine if the anomaly has occurred. Refer to the control storage and stability documentation for fluid stability guidelines once opened or reconstituted.
- Post this notification by each VITROS XT 3400 and/or XT 7600 System until this issue is resolved.
- Complete the enclosed Confirmation of Receipt form no later than **Month DD, 2022**.

Resolution

Ortho is currently investigating this issue; a follow-up communication will be released once our investigation is complete.

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 insert appropriate number.

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Questions and Answers

1. Are other VITROS Systems affected by this issue?

No, this anomaly only affects VITROS XT 3400 and VITROS XT 7600 Systems as these systems utilize a digital reflectometer.

2. Will performing routine Quality Control processing detect the issue?

Yes, routine Quality Control processing will help detect a potential shift in results. However, if there is a power event after Quality Control processing, the anomaly will not be detected until the next time your laboratory processes Quality Control fluids.

3. If the anomaly occurs, what is the impact to my results?

Ortho's investigation has shown that results can shift in either a positive or negative direction. The magnitude of the bias observed may exceed 3 Standard Deviations (SD).

4. Are all VITROS assays affected by this anomaly?

No, only the specific VITROS Microslide assays listed below are affected.

A1C1	BUBC	DGXN	PHBR	UPRO
ALC	CA	ECO2	PHOS	UREA
ACET	CHE	FE	PHYT	URIC
ALB	CHOL	GGT	PROT	GLU-CA
ALKP	CK	GLU	SALI	ALB-TP
ALT	CKMB	LAC	TBIL	ALTV-AST
ALTV	CREA	LDH/LDHi	THEO	GLU-CA
AMON	CRBM	LI	TIBC	TBIL-ALKP
AMYL	CRP	LIPA	TP	TRIG-CHOL
AST	dHDL	MG	TRIG	UREA-CREA

NOTE: VITROS® MicroTip, MicroWell, and Potentiometric MicroSlide (Na^+, K^+, Cl^-) assays are NOT affected as they do not utilize a digital reflectometer.

5. Is there a specific software version associated with this anomaly?

Our investigation into the root cause is ongoing. At this time, our data suggests that Software Versions 3.7.2 and below are affected by this anomaly.

6. What constitutes a system shutdown?

A system shutdown is typically performed during normal shutdown or emergency shutdown procedures. Refer to V-Docs or the Reference Guide for shutdown procedure information.

For VITROS XT 3400 Systems, refer to your Reference Guide (Pub. J64199), Chapter 5 - Startup and Shutdown, Shutdown the System (Normal Shutdown).

For VITROS XT 7600 Systems, refer to your Reference Guide (Pub. J64201), Chapter 5 - Startup and Shutdown, Shutdown the System (Normal Shutdown)

7. If my analyzer does not require a system shutdown, will I see a shift in my results?

No, Ortho's investigation has shown that the potential shift in results only occurs after performing a system shutdown.