

April x, 2015

URGENT FIELD SAFETY NOTICE **Software Anomaly using VITROS® Systems**

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you of an Urgent Field Safety Notice involving the following:

VITROS® Product	Affected Versions	Product Code	Unique Device Identifier No.
VITROS® 4600 Chemistry System	Software Version 3.2 & Below	6802445	10758750012343
VITROS® 5600 Integrated System	Software Version 3.2 & Below	6802413	10758750002740
Assay Data Disk (ADD)	All DRV versions that support product within expiry dating	6801876	10758750001576

The purpose of this notification is to inform you of a software anomaly regarding urine samples that require pretreatment.

Explanation

Ortho-Clinical Diagnostics, Inc. (OCD) has confirmed instances where the VITROS® System allowed urine samples for assays that required acidified pretreatment to be metered from the same sample container as assays that required no pretreatment when the sample was programmed.

Depending upon the assay, urine samples either need to be acidified, alkalized, extracted or require no pretreatment. The anomaly occurs for urine samples when using a downloaded sample program from a Laboratory Information System (LIS) and the sample program contains assays requiring sample pretreatment and assays requiring no sample pretreatment. Refer to Page 3 for a detailed description.

Impact to Patient Results

If this anomaly occurs, it is possible for VITROS® 4600 or 5600 Systems to process urine samples without the proper pretreatment, potentially leading to biased patient results. Refer to page 4 for the potential bias that may occur. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Required Actions

- **For urine patient samples that require pretreatment**, place each of the pretreated sample types in a separate container. It is acceptable for Ca, Mg, & PHOS to be metered from the same container. **Manually program the individual samples.** **NOTE:** An LIS download can be used to program urine samples only if assays requiring sample pretreatment and assays requiring no sample pretreatment are not included in the same sample program.
- Post this notification by each VITROS® 4600/5600 System in your facility or with the user documentation.
- Complete and return the Confirmation of Receipt form no later than **April xx, 2015.**

Resolution

The mitigation to this anomaly is currently under development. We will issue a follow up notification upon availability.

Contact Information

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

Sincerely,

Insert appropriate name

Insert appropriate title

Questions and Answers

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

Requirement for urine samples: Acidification pretreatment is required for Ca; no pretreatment is required for the GLU. An aliquot of the pretreated and untreated urine sample should be placed into separate containers.

The following is an example of how this anomaly occurs:

- A sample program is sent using an LIS download for a **urine** sample using VITROS® GLU Slides (GLU) and VITROS® Ca Slides (Ca).
- System incorrectly accepts the sample programming for both assays in the same container.
- System allows the urine sample to be metered from a single container and did not alert the operator of the error.

2. Are there any actions required?

For urine patient samples that require pretreatment:

- ✓ Use a separate container for each type of pretreatment
- ✓ **Manually program the assays.** It is acceptable for Ca, Mg, & PHOS to be metered from the same sample container.

NOTE: An LIS download can be used to program urine samples only if assays that require pretreatment are not included with assays that do not require pretreatment.

- ✓ Quality Control fluids are not affected.

As an example, it is acceptable for the following assays with urine patient samples to be programmed together because no pretreatment required:

- AMYL, GLU and UREA (BUN)
- AMPH, METH, and BARB

The following assays with urine patient samples that are pretreated (acidified) may be programmed together if the pH range is appropriate (as per the Instructions for Use):

- Ca
- Mg
- PHOS

The following assays with urine patient samples that are pretreated should be programmed individually using separate sample containers:

- Cortisol
- URIC

3. What urine assay results are potentially affected?

Because there are differing pretreatment requirements for urine samples for these assays, the following assay results are potentially affected:

Acidification Pretreatment	No Pretreatment Required					
Ca	AMYL	BENZ	GLU	METH	OP-HI	UPRO
Mg	AMPH	COCM	K ⁺	Na ⁺	PCP	UREA (BUN)
PHOS	BARB	CREA	mALB	OP-LO	THC	
NOTE: URIC, Cortisol and NTX are not affected by this anomaly						

Questions and Answers (continued)

4. What is the impact to patient sample results?

If this anomaly occurs, it is possible for VITROS® Systems to process urine samples without the proper pretreatment, potentially leading to biased patient results. The table below shows an example of biased results obtained during our internal investigation:

Assay	Recommended Urine Pretreatment	Unintended Pretreatment	Concentration with Recommended Urine Pretreatment		Maximum Bias Observed from Unintended to Recommended Pretreatment	
			Conventional	SI	Conventional	SI
Ca	Acidification	No Pretreatment	13.61 mg/dL	3.40 mmol/L	-8.76 mg/dL	-2.19 mmol/L
Mg	Acidification	No Pretreatment	14.16 mg/dL	5.83 mmol/L	-12.96 mg/dL	-5.33 mmol/L
PHOS	Acidification	No Pretreatment	134.22 mg/dL	43.34 mmol/L	-17.03 mg/dL	-5.50 mmol/L
AMYL	No Pretreatment	Acidification	433.0 U/L	433.0 U/L	-394.5 U/L	-394.5 U/L
UPRO	No Pretreatment	Acidification	5.5 mg/dL	0.055 g/L	Results below the Reportable Measuring Range	
mALB	No Pretreatment	Acidification	6.2 mg/dL	62 mg/L	+0.95 mg/dL	9.5 mg/L
THC	No Pretreatment	Acidification	19.0 ng/mL	19.0 µg/L	-3.9 ng/mL	-3.9 µg/L

5. Which sample types and VITROS® Systems are affected by this anomaly?

The LIS download anomaly only affects urine samples that require acidification or no pretreatment using VITROS® 4600, 5600 and 5,1 FS Systems and enGen™ Laboratory Automation Systems.

Customers using VITROS® 5,1 FS Systems and enGen™ Systems will be sent a separate notification with specific instructions for those systems.

6. Does this anomaly affect Quality Control programming?

This anomaly does not affect quality control programming, and therefore, there is no change when programming Quality Control fluids. Per the assay-specific Instructions for Use, the acidification pretreatment is recommended for patient samples only and quality control materials should not be pH-adjusted. Therefore, it is acceptable to continue to use either an LIS download or manual sample programming for Quality Control fluids.

7. Are User Defined Assays affected?

User Defined Assays (UDAs) for patient urine samples may also be affected depending upon the assay requests contained in the sample program. Management of User Defined Assays is specific for each assay. Testing UDAs in combination with all other assays needs to be assessed by your facility to determine required actions.

8. Can I determine if this anomaly had previously occurred on my system?

This anomaly occurred if urine samples were processed without the proper pretreatment. Review your laboratory protocols and discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.