Ortho Clinical Diagnostics

URGENT FIELD SAFETY NOTICE
Software Anomaly using VITROS® 5,1 FS Chemistry 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® 5,1 FS Chemistry System	Software Version 2.8 & Below	6801375	10758750001132
		6801890	10758750001644
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 or require no pretreatment. The anomaly occurs when manually programming urine samples or 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® 5,1 FS 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. **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.
- Review all pre-defined panels used for patient testing configured on your system. Remove assay buttons (targets) for any pretreated urine samples from the panel. Panels specifically used for Quality Control fluids are not affected.
- Post this notification by each VITROS® 5,1 FS 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 currently under development to prevent this anomaly will only allow Ca, Mg, and PHOS assays to be programmed <u>individually</u> for patient urine samples.

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 <mark>insert appropriate number.</mark>

Sincerely,

<mark>Insert appropriate name</mark>
<mark>Insert appropriate title</mark>

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Questions and Answers

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

<u>Requirement for urine samples:</u> 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 or a sample is manually programmed 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**.
  NOTE: An LIS download can be used to program urine samples <u>only</u> if assays that require pretreatment are not included with assays that do not require pretreatment.
- ✓ Review any pre-defined panels configured on your system, remove assay buttons (targets) for any pretreated urine samples from the panel. Panels specifically used for 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 should be programmed <u>individually</u> using separate sample containers:
> - Ca
> - Mg
> - PHOS
> - 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 is not affected by this anomaly						

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

   Customers using VITROS® 4600/5600 Systems and enGen™ Systems will be sent a separate notification with specific instructions for those systems.

6. **Does this anomaly affect Quality Control testing or programming?**

   This anomaly does not affect quality control programming, and therefore, there is no change when programming <u>Quality Control fluids</u>. 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 these 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.

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Questions and Answers (continued)

8. **What are the required actions if panels are configured and used on my VITROS® System?**

    Review all pre-defined panels used for patient testing of urine samples configured on your system. Remove assay buttons (targets) for any pretreated urine samples from the panel. Panels specifically used for Quality Control fluid testing are not affected and therefore, require no action.

    Refer to V-Docs for instructions on viewing or editing panels. To view the panels on your system from V-Docs:
    → Select '*Sample Programming*'
    → Select '*Panels*'
    → Select '*Editing a Panel*'

9. **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.

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