

April 13, 2015

URGENT PRODUCT CORRECTION NOTIFICATION **Software Anomaly using VITROS® Systems**

Please distribute this information to the appropriate personnel at your facility

Dear Customer,

This is to inform you of an Urgent Product Correction 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 pre-treatment.

Explanation

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

Depending upon the assay, urine samples either need to be acidified, alkalinised or require no pre-treatment.

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 pre-treatment and assays requiring no sample pre-treatment.

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 pre-treatment, 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.

Resolution

The correction currently under development to prevent this anomaly will only allow Ca, Mg, and PHOS assays to be programmed individually for patient urine samples.

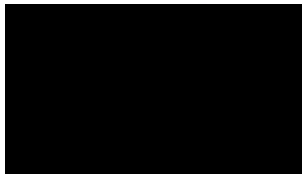
Required Actions

- 1) **For urine patient samples that require pre-treatment**, place each of the pre-treated sample types in a separate container. It is acceptable for Ca, Mg, & PHOS to be metered from the same container if the Mg pre-treatment protocol is used. **Manually program the individual samples.**
NOTE: An LIS download can be used to program urine samples only if assays requiring sample pre-treatment and assays requiring no sample pre-treatment are not included in the same sample program.
- 2) Review all pre-defined panels used for patient testing configured on your system. Remove assay buttons (targets) for any pre-treated urine samples from the panel. Panels specifically used for Quality Control fluids are not affected.
- 3) Post this notification by each VITROS[®] 5,1 FS System in your facility or with the user documentation.
- 4) Complete and return the **Customer Acknowledgement Form** within 2 business days to acknowledge your reading and understanding of this notice.

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 our Technical Solutions Centre at **1800 5646 766**.

Yours sincerely,



Cherie Yip
Regulatory Affairs Specialist

Questions and Answers

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

Requirement for urine samples: Acidification pre-treatment is required for Ca; no pre-treatment is required for the GLU. An aliquot of the pre-treated 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 pre-treatment:

- ✓ Use a separate container for each type of pre-treatment
- ✓ **Manually program the assays.** It is acceptable for Ca, Mg, & PHOS to be metered from the same sample container if the Mg pre-treatment protocol is used.
NOTE: An LIS download can be used to program urine samples only if assays that require pre-treatment are not included with assays that do not require pre-treatment.
- ✓ Review any pre-defined panels configured on your system, remove assay buttons (targets) for any pre-treated 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 pre-treatment required:

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

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

- Ca
- Mg
- PHOS

The following assay with urine patient samples that are pre-treated should be programmed individually using a separate sample container:

- URIC

3. What urine assay results are potentially affected?

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

| Acidification Pre-treatment | No Pre-treatment 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 | | | | | | |

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 pre-treatment, potentially leading to biased patient results. The table below shows an example of biased results obtained during our internal investigation:

| Assay | Recommended Urine Pre-treatment | Unintended Pre-treatment | Concentration with Recommended Urine Pre-treatment | | Maximum Bias Observed from Unintended to Recommended Pre-treatment | |
|-------|---------------------------------|--------------------------|--|--------------|--|--------------|
| | | | Conventional | SI | Conventional | SI |
| Ca | Acidification | No Pre-treatment | 13.61 mg/dL | 3.40 mmol/L | -8.76 mg/dL | -2.19 mmol/L |
| Mg | Acidification | No Pre-treatment | 14.16 mg/dL | 5.83 mmol/L | -12.96 mg/dL | -5.33 mmol/L |
| PHOS | Acidification | No Pre-treatment | 134.22 mg/dL | 43.34 mmol/L | -17.03 mg/dL | -5.50 mmol/L |
| AMYL | No Pre-treatment | Acidification | 433.0 U/L | 433.0 U/L | -394.5 U/L | -394.5 U/L |
| UPRO | No Pre-treatment | Acidification | 5.5 mg/dL | 0.055 g/L | Results below the Reportable Measuring Range | |
| mALB | No Pre-treatment | Acidification | 6.2 mg/dL | 62 mg/L | +0.95 mg/dL | 9.5 mg/L |
| THC | No Pre-treatment | 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 Quality Control fluids. Per the assay-specific Instructions for Use, the acidification pre-treatment 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.

Questions and Answers (continued)

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. 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 pre-treated 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 pre-treatment. Review your laboratory protocols and discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.