Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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URGENT PRODUCT CORRECTION NOTIFICATION

Software Anomaly during ADD Installation on VITROS® 5,1 FS Chemistry Systems using Software Versions 2.2.1 through 2.8

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

This is to inform you of an Urgent Product Correction Notification involving the following:

VITROS® Product	Product Code	Unique Device Identifier No.
VITROS® 5,1 FS Chemistry System	6801375	10758750001132
	6801890	10758750001644

The purpose of this notification is to inform you of a software anomaly that may occur during the installation of an Assay Data Diskette (ADD) using Software Versions 2.2.1 through 2.8. Please note that the anomaly is not caused by the ADD.

Summary of Anomaly

Ortho-Clinical Diagnostics, Inc. (OCD) received two customer complaints that occurred during the installation of an ADD. The following two scenarios were reported:

1. When a customer installed the ADD that supported the *new* VITROS® Chemistry Products HbA1c Reagent Kit, the VITROS® 5,1 FS System posted the following two condition codes (UA7-239 and SYD-024).

Our investigation determined that the condition codes occurred because the short assay name for the new VITROS® assay had the same name as a short assay name for a User Defined Assay currently in use on their VITROS® 5,1 FS System. As a result, the User Defined Assay target was deleted from their system.

2. When a customer installed the ADD, their system became unresponsive (screen freeze occurred) that required the VITROS® 5,1 FS System to be restarted; the system posted a condition code (UZ0-047) after the restart was initiated.

Due to a software coding error, for both scenarios, ALL default settings were restored from the ADD instead of retaining the user modified (configured) parameters and the operator was not alerted by the system. Refer to detailed information on page three.

Impact to Patient Results

If this anomaly occurs, the VITROS® 5,1 FS Systems may process samples using the default reporting units from the ADD instead of the user modified parameters (i.e., SI vs Conventional units). **NOTE:** When SYD-024 condition code occurs, the code description **indicates** that the data was restored; however, in the scenario above, user modified parameters were not retained.

It is important to note that the numerical results will be correct for the actual units reported on your VITROS® System. The reporting units may not be consistent with those expected due to user modification.

If all of the reporting units on your VITROS® 5,1 FS System are correct for your facility, then the anomaly has not occurred. If the units for all of your assays have changed to the conventional (default) units, the anomaly likely occurred. Review all results reported on your VITROS® System versus the units expected on your LIS since the last time you installed an ADD. If any discrepancies are identified, discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Actions Required from You

1. **Prior to installing an ADD that supports a new assay;** verify that the new assay does not have the same name as any UDA currently on your system. If the names are the same, you are required to do the following:
   (i) Rename the UDA using a name that is different from the short assay name for any VITROS® assay
   (ii) Install the ADD

2. **Until a future software version is installed, if you experience a UA7-239 condition code or your system becomes unresponsive during an ADD installation**, you are required to do the following if your system is configured to use reporting units that are not the default units on the ADD:
   - If your system is unresponsive, restart your system.
   - Verify that the reporting units for all assays on your system are correct for your facility.
   - If you discover a discrepancy or your VITROS® 5,1 FS System utilizes **other** user modified parameters, verify that all of your user-modified parameters are correct. **If any parameters have changed:**
     1. Install the backup configuration files to restore your user modified parameters **OR** reenter user modified parameters and/or UDA parameters
     2. If appropriate, rename your UDA assay as indicated above.
     3. Re-install the ADD
     4. Calibrate only UDA assays that were renamed either by manual entry of calibration parameters or performing a calibration

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.

Rate of Occurrence

Analysis of e-Connectivity® data estimates the probability of occurrence of this anomaly to be approximately **0.002%** of all VITROS® 5,1 FS Systems (2 out of 82,750 ADD installations).

Resolution

OCD determined that the root cause of this anomaly is due to an error in the software code. The resolution is currently under development and will be available in a future version of software. We will notify you upon availability.

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 **1800 5646 766** at any time.

Yours sincerely,

[redacted]

Cherie Yip
Regulatory Associate

Questions and Answers

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

Scenario 1:

Actions: When a customer installed the ADD that supported the *new* VITROS® Chemistry Products HbA1c Reagent Kit, their VITROS® 5,1 FS System posted the following condition codes:

- UA7-239 (User Defined Assay or Diluent name needs to be changed)
- SYD-024 (Database update failed; previous assay data restored)

Consequences: The condition codes occurred because the assay name for the new VITROS HbA1c assay (Hb, A1c) had components of an assay name for a User Defined Assay (Hb) currently in use on their VITROS® System.

As a result, the reporting units for all VITROS® MicroSlide and MicroTip assays were changed back to default settings on the ADD instead of retaining their user modified parameters. It was noted that results for an assay on their VITROS® 5,1 FS Systems were correctly reported, (but in mg/L) while the same results processed through the Laboratory Information System (LIS) were reported in mg/dL. In addition, all User Defined Assays were deleted on their system.

Scenario 2:

Actions: A customer reported that during the installation of an ADD, their system became unresponsive (screen freeze occurred) that required the VITROS® 5,1 FS System to be restarted. The following condition code was posted:

- UZ0-047 (An RDS file condition occurred)

Consequences: The reporting units for CRP results had reverted back to the default settings (mg/L) instead of the user modified settings (mg/dL).

2. If the anomaly occurs, how is my system affected?

If your system does not use user modified parameters, there will be no changes to your system. If you had modified parameters, they may revert back to the default parameters. The enGen™ Laboratory Automation System is not affected as the anomaly is associated with VITROS® Software.

3. What are User-Configured (Modified) Parameters?

Refer to the "*About Options and Configuration*" section in your VITROS® 5,1 FS Chemistry System Quick Reference Guide for descriptions of user-configurable items on your system.

4. Will Quality Control testing identify if the reporting units have changed?

If using a Laboratory Information Systems (LIS) for Quality Control, the next time you process QC samples, the results should be flagged as outside of QC limits based on the differences in

reporting units.
NOTE: If you utilize the QC program on the VITROS® System, the unit change may not be identified as the numerical results will change appropriately with the reporting units.

5. **How can I determine if this anomaly occurred on my VITROS® System?**
   If all of the reporting units on your VITROS® 5,1 FS System are correct for your facility, then the anomaly has not occurred.

   If the units for all of your assays have changed to the conventional (default) units, the anomaly may have occurred. Review all results reported on your VITROS® System since the last time you installed an ADD. If any discrepancies are identified, discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

   As an example, a VITROS® System is configured to report C3 results in default units (mg/dL). If the anomaly occurred, the VITROS® System generated a result of 55 mg/dL. The result was uploaded to the LIS as 55 mg/dL. The LIS is configured in alternate units (mg/L) and was also configured to accept the numerical value, not the units. Therefore, the result in the LIS would be 55 mg/L (instead of the expected 550 mg/L).

6. **What should I do if an Assay Short Name for a VITROS assay is the same as a User Defined Assay on my system?**
   If you are currently using a User Defined Assay (UDA), please verify that the short assay name for your UDA is not the same as the short assay name for any VITROS® assay. If the short assay name for your UDA is the same, you will need to rename the UDA to a name that differs from all other assay names on your VITROS® System. Please follow the instructions listed in the Required Actions section.

7. **When will this anomaly be resolved?**
   The resolution is currently under development and will be available in a future version of software. We will notify you upon availability.