URGENT

Ortho Clinical Diagnostics

October xx, 2018

URGENT FIELD SAFETY NOTICE

Incorrect Determination of On-Analyzer Stability Time on VITROS® 5,1 FS Chemistry Systems

Dear Customer,

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics initiated this Urgent Field Safety Notice to inform you of a software anomaly. Under specific conditions, the VITROS® 5,1 FS Chemistry System may incorrectly extend the on-analyzer stability time for a loaded VITROS Reagent*.

VITROS System	Affected Software	Product Code	Unique Device Identifier No.
VITROS® 5,1 FS Chemistry System	Version 3.0 & below	6801375	10758750001132

*VITROS Reagents are defined as individual MicroSlide cartridges, MicroTip packs, MicroTip Partnership Assays (MPAs) and User Defined Assays (UDAs), and/or Diluent packs.

Background Information

When VITROS Reagents are loaded, the VITROS 5,1 FS System is designed to automatically determine:

- If a reagent pack or cartridge is full or partially used.
- If the Shelf Expiration Date for the reagent is included on the ADD loaded on your system.
- The on-analyzer stability time, which is the amount of time the reagent may remain on the analyzer to ensure optimal reagent performance.

Description of Anomaly and Impact to Results

Our investigation confirmed that under specific scenarios, a software anomaly will occur causing the VITROS 5,1 FS System to incorrectly determine the reagent's on-analyzer stability time. The identified scenarios are outlined in the Question and Answer Section on Page 3.

When the anomaly occurs, the system could use reagents past their on-analyzer stability time without alerting the user with a condition code or flagging the associated results with an RE (Reagent Expired) code.

In the event reagents are used beyond their specific on-analyzer stability times, the associated test results may be affected.

Rate of Occurrence

Based on condition code data obtained via e-Connectivity®, approximately 97% of all cartridges/packs are depleted *before* their expected on-analyzer expiration time, therefore the results would not be affected by this anomaly.

The estimated frequency of occurrence of a VITROS Reagent being used after its expected on-analyzer stability time due to this anomaly is approximately 1 in 1.5 million cartridges/packs.

Ortho has received no customer complaints related to this anomaly on VITROS 5,1 FS Systems.

Detection

Any occurrence of this anomaly is not easily identifiable. However, performing daily quality control testing will help to assess if reagents are performing within expectations.

Resolution

The resolution to this anomaly is included in Software Version 3.1 (MOD B9). This field safety notice is being issued together with a communication about Software Version 3.1 (Ref. CL2018-112a) and Release Notes for the new software that resolves the anomaly.

We anticipate that the software will be released via download during the week of October 29, 2018. Software Kits will be issued following the download release. Until MOD B9 is loaded on your VITROS 5,1 FS System, to prevent occurrence of the anomaly, please follow the instructions below.

REQUIRED ACTIONS

Reset System and Evaluate current reagent status (need to do one time only):

1. To reset your VITROS 5,1 FS System, after ensuring testing is complete, perform a Normal Shutdown and startup of your system.
2. Based on your typical usage, assess which, if any, reagents currently loaded on your system are at risk of exceeding on-analyzer stability time prior to being fully depleted (e.g., low-volume assays or assays with short on-analyzer stability time, such as VITROS CRP). **NOTE:** Your usage may be such that all reagents are used prior to exceeding on-analyzer stability time and that no packs/cartridges are "at risk."
3. Record the test count of each “at risk” reagent on the system (if any), and then remove the "at risk" reagents from your system. **Note:** MicroTip diluents do not display a test count.
4. Request credit for unused tests by using the Confirmation of Receipt form.

To prevent the occurrence of this anomaly until the new software version is installed:

For All Reagent Types:

- Ensure that the most recent ADD (i.e., latest DRV#) is installed prior to loading new lots of all reagents.
- Newly opened reagents should be loaded normally using the Load/Unload process. It is not necessary to perform any additional Shutdowns for reagents loaded using the Load/Unload process.
- To load partially used reagents, *or* full reagents that have been previously loaded on another system, first ensure all testing is complete. Do not use the Load/Unload process button. You must use Manual Load process following the V-docs Manual Load instructions for your system and the additional instructions below.

Manually Loading MicroSlide Cartridges:

1. In Reagent Management, use the Manual Load process. Ensure that all information on the Manually Load Cart dialog screen is complete and accurate for each cartridge loaded.
2. Touch the Status button on the Reagent Management screen.
3. *When the reagent inventory process has been completed*, return to the System Status screen and immediately perform Normal Shutdown, and then startup your VITROS 5,1 FS System.

Manually Loading Reagent Packs (MicroTip, Diluents):

IMPORTANT NOTE: To load partially used packs, packs used on another VITROS System, and packs that have been removed from the same system for any reason (including to remove "Bubbles"), always use the Manual Load Process, specifying the barcode, shelf expiration and open date when prompted to do so.

On the Reagent Management screen, use the Manual Load process. Ensure that all information on the Manually Load Pack dialog is complete and accurate for each pack loaded.

- If any full or partial pack has been previously loaded on the same analyzer, the shelf expiration and open dates will automatically be populated once the barcode has been entered. It is **not necessary** to shut down and restart your system.
- If any full or partial pack has not been previously loaded on the same analyzer, you must complete the open date on the Manually Load Pack dialog, return to the System Status screen and immediately perform a Normal Shutdown, and then startup your VITROS 5,1 FS System.

ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **October xx, 2018**.
- Post this notification by each VITROS 5,1 FS System in your facility or with your user documentation.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

In the event reagents are used beyond their specific on-analyzer stability times (OAS), the associated test results may be affected. The potential impact to test results that may be observed is obtainable from Ortho Care Technical Solutions Center.

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* / *insert signatory if required*

Questions and Answers

1. **What is "on-analyzer stability time"?**

   VITROS Reagents all have a specific "on analyzer stability time," which is the amount of time the reagent may remain on the analyzer to ensure optimal reagent performance. This varies by reagent and is different from the shelf expiration date.

2. **How is the analyzer supposed to work with regard to on-analyzer stability time?**

   The analyzer is intended to keep track of on-analyzer stability time regardless of whether a reagent is full or partially used and loaded using the Load/Unload or Manual Load process.

3. **What scenarios can cause the anomaly to occur?**

   Ortho has discovered several scenarios where the open expiration of a reagent may be incorrectly set.

   The scenarios that may cause this issue are dependent on numerous factors, such as the actual supply slot the reagent was loaded into, or whether the slot had contained a previous reagent that had the open date manually entered. The scenarios that can cause the anomaly are listed below.

   IMPORTANT to NOTE: The instructions provided under Required Actions will prevent your system from using reagents incorrectly beyond the on-analyzer stability time indicated in the Instructions for Use.

Scenario One

If the shelf expiration date for a reagent lot is not supported by the currently loaded ADD, the open expiration date for a partially used reagent of the unsupported lot will be incorrectly assigned as if the reagent was full.

Scenario Two

The expiration date for a partially used MicroSlide cartridge will be incorrectly reset to the expiration date of a new cartridge if:

- The slide supply containing the cartridge is re-initialized, ***and***
- After the cartridge is re-inventoried, the slide count is different by more than +-3 slides compared to the previous count, ***and***
- The same slot previously contained a cartridge that had been manually loaded with the open date manually entered, ***and***
- A shutdown and restart of the system had not been performed since the previous manual load event.

Scenario Three

The open expiration date for a partially used MicroSlide cartridge loaded without specifying the date opened will be incorrectly assigned as if the reagent was full and given full on-analyzer stability time. This occurs when a cartridge containing a single slide is loaded without specifying the date opened.

Confirmation of Receipt – Response Required

Communication ID: 2018-194 Date of Issue: 2018-10-xx

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*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **xx-OCT-2018**

Send to: *Insert name* e-Mail Address: insert email address Fax: Insert number

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____

Please Confirm

I received the Urgent Field Safety Notice with information that under specific circumstances, VITROS 5,1 FS Systems may incorrectly determine the on-analyzer stability time for VITROS Reagents (MicroTip packs, MicroSlide cartridges and/or Diluents).

I understand the information provided in the customer letter and will follow the instructions to evaluate current status on our VITROS System(s) and help mitigate a potential occurrence of the anomaly until new software is installed.

Please choose from the following:

☐ My laboratory has identified "at risk" packs/cartridges, removed them from our system, and requests credit for the unused tests in open reagents (only) listed below.

☐ My laboratory has not identified or removed any "at risk" packs/cartridges from our system and does not require credit for unused tests.

Please enter the product name/Product Code (REF number) and Lot Number for each partially used product as well as the remaining quantities of tests in each partially used pack/cartridge.

Product Name/Product Code/LOT	Quantity of Unused Tests in Open Reagents (only)
VITROS / /	
VITROS / /	
VITROS / /	
VITROS / /	
VITROS / /	
VITROS / /	

Print Name: _____

Signature: Required
Your signature confirms that you have received and understand this communication.

Phone Number: _____ Date: _____

Your Comments: _____

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent: _____

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	