



October xx, 2018

URGENT FIELD SAFETY NOTICE

**Incorrect Determination of On-Analyzer Stability Time
on VITROS® 3600 Immunodiagnostic 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® 3600 Immunodiagnostic 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® 3600 Immunodiagnostic System	Version 3.3.1 & below	6802783 6802914	10758750002979 10758750007103

*VITROS Reagents are defined as individual MicroWell packs and/or Diluent packs.

Background Information

When VITROS Reagents are loaded, the VITROS 3600 System is designed to automatically determine:

- If a reagent pack 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 a specific scenario, a software anomaly will occur causing the VITROS 3600 System to incorrectly determine the reagent’s on-analyzer stability time. The identified scenario is described in the Questions and Answers 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 98% of all 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 1.9 million packs.

Ortho has received no customer complaints related to this anomaly on VITROS 3600 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 will be included in the next version of software that is expected to be released in December 2018.

In the interim, 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 3600 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)
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.
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:

- Ensure that the most recent ADD (i.e., latest DRV#) is installed prior to loading new lots of all reagents by using only the "All Assay Data" load option.
- 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 Reagent Packs (MicroWell, 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 3600 System.

ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **October xx, 2018**.
- Post this notification by each VITROS 3600 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 the scenario below where the open expiration of a reagent may be incorrectly set.

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 that can cause the anomaly

The open expiration date for a partially used reagent will be assigned as if the reagent was full, and the reagent will be incorrectly given a full on-analyzer stability time. This occurs when:

- A less than full MicroWell pack is loaded without specifying the date opened, **and**
- Foam, film or bubbles are detected, **and**
- The pack is removed to eliminate the foam, film or bubbles, **and**
- The pack is reloaded without using the manual load process

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 Field Safety Notice with information that under specific circumstances, VITROS 3600 Systems may incorrectly determine the on-analyzer stability time for VITROS Reagents (MicroWell packs 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, 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 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.

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

Print Name: _____

Phone Number: _____ Date: _____

Your Comments:

Signature: _____

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

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