



## IMPORTANT

Ortho Clinical Diagnostics

January 2018

### IMPORTANT PRODUCT CORRECTION NOTIFICATION Incorrect Determination of On-Analyser Stability

Dear Customer,

This notification is to inform you of a potential software anomaly. Under specific conditions, the VITROS Systems (listed below) will incorrectly set the on-analyser stability time of a reagent pack as 24 hours.

Affected VITROS Systems	Affected Software	Product Code	Unique Device Identifier No.
VITROS® 5,1 FS Chemistry System	Versions 3.0 & below	6801375 6801890	10758750001132 10758750001644
VITROS® 4600 Chemistry System	Version 3.3.1 & below	6802445	10758750012343
VITROS® 5600 Integrated Chemistry System	Version 3.3.1 & below	6802413 6802915	10758750002740 10758750007110
<b>Note:</b> This anomaly only affects the on-analyser stability for <b>VITROS Chemistry Products ASO Reagent and VITROS Chemistry Products VANC Reagent</b> .			

#### Background Information

Once a VITROS ASO or VANC Reagent Pack is loaded, the VITROS System automatically determines the appropriate on-analyser stability time. The on-analyser stability time is continuously adjusted based upon the number of days the reagent pack is on the analyser and the number of tests remaining in the pack. Refer to Reagent Management for the actual on-analyser stability time remaining for each reagent pack.

#### Description of Anomaly

Our investigation confirmed that under specific scenarios, the VITROS System incorrectly shortened the on-analyser stability to 24 hours if the following occurs:

##### Scenario 1:

- A new Generation (GEN) of VITROS VANC or ASO Reagent is loaded on the system prior to installing the supporting Assay Data Diskette (ADD).  
**NOTE:** On the Reagent Management screen, the count is displayed as "0" and the status is displayed as "unknown".
- An ADD that supports the new GEN is then installed while the affected pack is still on board the system.

##### Scenario 2:

- Bubbles or foam are detected by the system in a VITROS ASO or VANC Reagent Pack.  
**NOTE:** On the Reagent Management screen, the count is displayed as "0" and status is displayed as "bubbles".
- Any ADD is then installed while the affected pack is still on board the system.

**In both scenarios, the system incorrectly sets the on-analyser stability time to 24 hours instead of 7 days (VANC) or 21 days (ASO).**

## Detection

When the issue occurs, the system will alert the operator via the following condition codes:

VITROS 5,1 FS Systems	<b>PVD-013</b>
VITROS 4600/5600 Systems	<b>PV8-093</b> (Earliest Threshold default time is 24 hours)

## Impact to Results

This anomaly will not adversely affect results for ASO and VANC assays.

## Rate of Occurrence

Based upon six months of e-Connectivity<sup>®</sup> data, our data analysis suggests the rate of occurrence for this anomaly to be approximately **2 possible occurrences out of 1000** VITROS ASO or VANC Reagent Packs loaded.

## REQUIRED ACTIONS

- Install the most recent ADD (i.e., latest DRV#) on your VITROS System **prior to** loading new GENs of reagent packs.  
For VITROS 4600/5600 Systems: use the "All Assay Data" load option.
  - **Unload reagent packs with a status of "Unknown", "Bubbles" or "Inv??" prior to loading any ADD. Install the ADD, and then reload the reagent pack to allow the system to correctly determine the on-analyser time limit.**
  - If you experience the anomaly, you will be alerted with a PV8-093 or PVD-013 attention code:
    - Use the reagent pack until it reaches its on-analyser time limit\*.
    - It is acceptable to use the reagent pack on an alternate VITROS System provided it is manually loaded using the correct open date.
- \*NOTE:** Ortho will credit your account for any reagent packs that are within expiry date, yet unusable on your system due to this anomaly.
- Complete and return the Confirmation of Receipt form no later than **January 19, 2018**.
  - To report future occurrences, please retain a copy of the Confirmation of Receipt form
  - Post this notification by each VITROS System in your facility or with the user documentation.
  - Please forward this notification if the product was distributed outside of your facility.

## Resolution

The resolution to this anomaly will be contained in the next version of software currently under development. In the interim, Ortho will send you a Technical Bulletin with this information.

## Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care<sup>™</sup> Technical Solutions Centre at 1800-5646-766

Sincerely,

  
Jon Wong

QA Manager