

Date November 2016

Issue Description This notification provides additional information to a Product Correction Notification that Ortho Clinical Diagnostics (Ortho) issued in December 2015 (Ref. CL2015-201) regarding the clarification of operator actions for wash errors. Since that time, Ortho has been monitoring the occurrence of U90-382 or 6LU condition codes associated with wash errors. We observed an increase in wash errors for VITROS Chemistry Products PHYT Slides.

Affected Products

Product (Unique Device No.)	Affected Data Release Versions (DRV)	Affected Reagents (Unique Device No.)
Assay Data Diskette (ADD) Product Code: 6801876 (10758750001576)	5909 & Below	VITROS Chemistry Products PHYT Slides* Product Code: 8298671 (10758750004690)
Calibration Diskette Product Code: 8716607 (10758750005116)		

***This information is applicable for all current (in date) lots.**

Background Information

VITROS PHYT Slides quantitatively measure phenytoin (PHYT) concentration in serum and plasma using VITROS 250/350/950/5,1 FS/4600/5600 Systems. During slide processing VITROS Immuno-Wash Fluid is added to the slide.

Investigation

As part of the corrective and preventative actions for the previous field action, Ortho observed that wash errors were occurring at a higher than expected rate for VITROS PHYT Slides. We determined that VITROS Systems could sometimes log false wash errors.

Resolution

Ortho has identified an improvement to the wash algorithm that will help reduce false wash errors while not compromising the detection of true wash errors. This improvement involves a change to the Magenta Wash Tolerance (MWT) limit and will be implemented on Calibration Diskette/ADD DRV 5910 and above. Please install this Calibration Diskette or ADD upon availability and recalibrate your VITROS PHYT Slides.

Impact to Results

If a U90-382 or 6LU condition code is generated, the VITROS System suppresses the result and "No Result" is reported. A review of previously reported results is not necessary as the result is suppressed and flagged with a Wash Error (WE) code.

Required Actions

- Install Calibration Diskette or ADD DRV 5910 or above on your system:
 - Automatic download will be available for e-Connected systems as of December 2, 2016.
 - Calibration Diskette and/or ADD will also be sent to your facility upon availability.

IMPORTANT TO NOTE: After loading DRV 5910 (or above) for the first time, VITROS PHYT Slides will un-calibrate and will require recalibration. In the interim, it is acceptable to continue to use the product.

**Required
Actions
(continued)**

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- Following a successful calibration and quality control assessment, it is acceptable to use your inventory of VITROS PHYT Slides.
 - Post this notification by your VITROS System or with your user documentation.
 - Complete the Confirmation of Receipt form and return by **November 25, 2016**.
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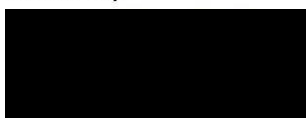
**Contact
Information**

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 additional questions, contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Enclosure:

Confirmation of Receipt form

Sincerely,



Jon Wong, Quality Manager

17 November 2016

Questions and Answers

1. What is the Magenta Wash Tolerance Limit?

The Magenta Wash Tolerance (MWT) limit helps to ensure that an adequate volume of VITROS Immuno-Wash Fluid is applied to the slide so that incorrect results are not reported. If the response ratio for the signal exceeds the tolerance, a wash error flag (i.e., WE U90-382 or 6LU) is generated by the VITROS System and the result is suppressed (i.e., No Result).

2. What is the purpose of VITROS Immuno-Wash Fluid?

During slide processing:

- 12 µL of VITROS Immuno-Wash Fluid is added to the slide.
- The wash detection dye is read by the system and assessed using the Magenta Wash Tolerance (MWT) limit.
- A condition code is generated if a wash fails the tolerance limit and the result is suppressed.

3. Why is it necessary to re-calibrate my VITROS PHYT Slides?

The system obtains the MWT limit from the Calibration Diskette or ADD. In order to reduce the occurrence of false wash errors, re-calibration is required so that your VITROS System utilizes the revised MWT limit.

NOTE: The MWT limit was inadvertently flagging slides that had an acceptable volume of wash fluid; revising the limit will help to reduce the potential for false wash errors.

4. How is this action related to the previous field action?

The following is a chronological sequence of events related to this issue:

- **December 2015:** Ortho issued a Product Correction Notification (Ref. CL2015-201) regarding the clarification of operator actions following wash error condition codes.
- **May 2016:** Ortho issued a follow up notification (Ref. CL2016-072) and Technical Bulletin to provide operator actions following U90-382 condition codes.
- **November 2016 (Present):** As part of the corrective and preventative actions for the previous field action, Ortho observed an increase in false wash errors using VITROS PHYT Slides. To help reduce the occurrence of false wash errors, the MWT limit for VITROS PHYT Slides will be revised on Calibration Diskette/ADD DRV 5910 and above.