Ortho Clinical Diagnostics	**URGENT FIELD SAFETY NOTICE** **Clarification of Operator Actions for Wash Error (WE) Condition Codes using VITROS® Systems** **Immediate Action Required**

Date Issued xx December 2015

Product

Product Name	Product Code	Unique Device Identifier No.
VITROS® 250 Chemistry System	8132086	10758750004409
	6801759	10758750001330
VITROS® 350 Chemistry System	6802153	10758750002054
VITROS® 5,1 FS Chemistry System	6801375	10758750001132
	6801890	10758750001644
VITROS® 4600 Chemistry System	6802445	10758750012343
VITROS® 5600 Integrated System	6802413	10758750002740

Issue Explanation

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics, Inc. (Ortho) initiated this Urgent Field Safety Notice due to the need to clarify operator actions following **U90-382** or **6LU** condition codes generated by the systems listed above.

- U90-382 or 6LU condition codes are associated with wash errors that may occur when using VITROS® Chemistry Products for immuno-rate assays (i.e., VITROS® CRBM, CRP, DGXN, and PHYT Slides).
- If a U90-382 or 6LU condition code (i.e., associated with a wash error) occurs, the condition code text located on the VITROS® System and other user documentation indicates to dilute the sample. However, dilution may not be the appropriate action for all scenarios

Impact to Results

- If a U90-382 or 6LU condition code is generated, the VITROS® System properly suppresses the result and "No Result" is reported. The result is flagged with a Wash Error (WE) code.
- If the analyte concentration is not above the measuring range and the sample is diluted and reprocessed, the results may be erroneously reported as within or below the measuring range. In this scenario, dilution is not an appropriate action and the result should not have been reported.
- Events that occurred prior to this communication are not easily identifiable; thus, a review of previous results may be impractical. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Required Actions

For results flagged with a Wash Error (WE) code:

- Follow the recommended actions described in your user documentation.
- If a single sample has been diluted and reprocessed:
  - If the calculated result on the diluted sample exceeds the measuring range, the result is acceptable.
  - If the WE code reoccurs on the same sample or the calculated result does not exceed the measuring range, use an alternative method to perform the assay.
- Post this notification by your VITROS® System(s) or with your user documentation.
- Complete and return the Confirmation of Receipt form by **insert appropriate date**.

Contact Information

If you have any questions, contact Customer Technical Services at *insert appropriate phone number*.

Enclosure: Confirmation of Receipt form

Questions and Answers

1. What are U90-382 or 6LU condition codes?

U90-382 or 6LU condition codes are associated with wash errors when using slides that are immuno-rate assays.

Type of System	Condition Code Displayed (Description)	Report Code Associated with Suppressed Result
VITROS® 250, 350 Systems	**6LU** (IR WASH DETECTION * IR wash failed)	Wash Error (WE)
VITROS® 4600, 5600 and 5,1 FS Systems	**U90-382** (IR wash error)	
NOTE: VITROS® CRBM, CRP, DGXN, and PHYT Slides are categorized as immuno-rate assays.		

2. How can an erroneous result be reported?

The following two scenarios are examples of how an erroneous result could be reported using a VITROS® PHYT Slide:

Scenario # 1:

Action	Impact to Results
U90-382 or 6LU condition code occurs	"No Result" is reported
Operator dilutes the sample (2X) and test is repeated	Calculated result is <6 µg/mL (<23.76 µmol/L)

Since the calculated result is less than the measuring range, the WE report code associated with the result for the neat sample was not due to a high concentration of phenytoin.

Scenario # 2:

Action	Impact to Results
U90-382 or 6LU condition code occurs	"No Result" is reported
Operator dilutes the sample (2X) and test is repeated	Calculated result is 10.00 µg/mL (39.60 µmol/L)

If the calculated result for a diluted sample is within the measuring range, but the neat analyte concentration is expected to be outside the range, then the WE code associated with the result for the neat sample was not due to a high concentration of phenytoin.

In both scenarios, the "No Result" associated with the neat sample was not due to a sample with a high concentration of phenytoin, but instead it may be due to a possible interferent. Therefore, dilution was not an appropriate action and the result should not have been reported.

3. Where can I find suggested operator actions to take following a WE report code?

Condition Code instructions (i.e., "Things to Do") are located in the condition code text located on your VITROS® System. They are also provided in your system's User documentation and the VITROS Flags and Codes on Reports Summary (J12329).

Questions and Answers (continued)

4. What can cause a wash error to occur?

A wash error may occur due any of the following scenarios:

- Immuno-Rate wash fluid (IWF) was detected as insufficient.
- Wash Fluid module was not functioning properly
- Calibration was performed using a different Calibrator Kit Lot than was selected in calibration programming.
- Calibration was not performed when a new lot of IWF was introduced.
- Sample may contain an interferent.
- Sample may contain a low total protein concentration.
- Sample may contain an analyte concentration outside of the upper limit for the measuring range.

5. What is Ortho doing to resolve this issue?

In the near future, we will send a Technical Bulletin containing the clarification for operator actions. Ortho will also issue notifications when the user documentation is revised and the system software includes the new condition code text for operator actions.

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

Ortho Clinical Diagnostics

Clarification of Operator Actions for Condition Codes using VITROS® Systems

*Please return completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than*: **DD-MM-YYYY**

Send to: Name e-Mail Address: email address Fax: Fax Number

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2015-201_EU) regarding the need to clarify operator actions for U90-382 or 6LU condition codes. I understand that for results flagged with a WE condition code, if the sample is diluted and reprocessed, and the calculated result is within or below the measuring range, I must not report the result.

Your signature provides confirmation that you have received and understand this notification.

Your Name: _____ Signature: _____

Required if sent by fax or a scanned PDF

Phone Number: _____ Date: _____

Your Comments: _____

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: _____