Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

December 21, 2015

URGENT PRODUCT CORRECTION NOTIFICATION

Clarification of Operator Actions for Wash Error (WE) Condition Codes using VITROS® Systems
(Immediate Action Required)

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

Ortho Clinical Diagnostics, Inc. (Ortho) initiated this Urgent Product Correction Notification 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

Affected Products

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

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.

Actions Required from You

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

1. Follow the recommended actions described in your user documentation.

2. If a single samples 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.

3. Post this notification by your VITROS® System(s) or with your user documentation.

4. Complete and return the **Customer Acknowledgement Form** within **(2) two business days** to acknowledge your reading and understanding of this notice.

If you have any questions, please contact Customer Technical Services at **1800 5646 766**.

Yours sincerely,

[redacted]

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Lee, Ching Hwee
Senior Regulatory Affairs Specialist

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 <u>less than</u> the measuring range, the WE report code associated with the result for the neat sample was <u>not</u> 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 <u>within</u> 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 <u>not</u> due to a high concentration of phenytoin.

In both scenarios, the "No Result" associated with the neat sample was <u>not</u> 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.