Ortho Clinical Diagnostics	**IMPORTANT NOTIFICATION: Technical Bulletin: Update to IR Wash Error Operator Actions for VITROS® Systems**

Date Issued June 1, 2016

New Technical Bulletin

New Technical Bulletin	Pub. No.	Pub. Date
Update to IR Wash Error Operator Actions	J56080	2016-03-07

Summary

The enclosed Technical Bulletin provides information on *new recommended operator actions* following U90-382 or 6LU condition codes on VITROS Systems. U90-382 or 6LU condition codes are associated with Wash Error (WE) codes on VITROS Systems listed in the table below. This is a follow up to a previous notification (Ref. CL2015-201) in which you were instructed to follow the recommended actions described in your user documentation.

IMPORTANT NOTE: *Please read the Technical Bulletin in detail and follow the recommended actions until implemented in a future software version.*

Retain the Technical Bulletin with your system documentation binder until the appropriate User Guides and publications have been revised.

Products Impacted

Product Name
VITROS 250 Chemistry System
VITROS 350 Chemistry System
VITROS 5,1 FS Chemistry System
VITROS 4600 Chemistry System
VITROS 5600 Integrated System

Contact Information

If you have any technical questions regarding this notification, please contact the Ortho Technical Solutions Center at 1-800-421-3311.

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Enclosure:
Technical Bulletin: (Pub No. J56080)

Technical Bulletin

VITROS® 5600 Integrated System
VITROS® 4600 Chemistry System
VITROS® 5,1 FS Chemistry System
VITROS® 350/250/250AT Chemistry Systems

Pub. No.: J56080EN
Issued: 2016-03-07

Update to IR Wash Error Operator Actions

Purpose

This Technical Bulletin contains information regarding the WE code, as well as new Operator Actions recommended when WE codes, or condition codes U90-382 or 6LU occur on the VITROS® 5600 Integrated System, VITROS® 4600 Chemistry System, VITROS® 5,1 FS Chemistry System, or VITROS® 350/250/250AT Chemistry Systems. The updated actions will be included in future software releases.

In this Technical Bulletin, the names of the systems are shortened to VITROS® 5600 System, VITROS® 4600 System, VITROS® 5,1 FS System, and VITROS® 350/250/250AT Systems.

How to Use this Technical Bulletin

Read this Technical Bulletin in detail. For future reference, file this Technical Bulletin in your System Documentation Binder.

Updated WE Code Actions

A Wash Error (WE) code occurs if the Immuno-rate (IR) wash was invalid as a result of one of the following occurrences:

- Sample contains a concentration of analyte exceeding the measuring range
- Insufficient wash fluid
- Interfering substance in the sample
- The Wash Fluid module was not functioning properly
- Incorrect calibration information
- Calibration was not performed when a new lot of IWF was introduced
- Sample might have a low total protein

For results flagged with a Wash Error (WE) code, perform the following actions in the order given:

1. Repeat the test
2. Dilute the sample and repeat the test. (The only purpose of the dilution is to determine if the WE code was caused by the analyte concentration exceeding the upper measuring range.)

3. Change the IWF TIP
4. Change the IWF RESERVOIR
5. Verify that the IWF RESERVOIR is seated properly
6. Verify the analyte was calibrated using the new lot of IWF
7. Run a Total Protein test on the patient sample.

Updated U90-382 and 6LU Operator Actions

If a U90-382 condition code occurs on the VITROS® 5600 System, VITROS® 4600 System, or VITROS® 5,1 FS System, or a 6LU code occurs on the VITROS® 350/250/250AT Systems, refer to the following table:

Possible Causes	Things to do
1. If this condition code occurs for only one sample, the measured analyte in the sample **may** be elevated.	1. Program the sample for dilution and rerun the sample. The only purpose of the dilution is to determine if the WE code was caused by the analyte concentration exceeding the upper measuring range. Refer to the Instructions for Use for dilution information.
2. If this code occurs for only one sample, the sample may have an interferent. Verify that the patient is not receiving Digibind if code occurs on DGXN.	2. Patients receiving Digibind cannot be assayed for DGXN until the Digibind clears. Refer to the Instructions for Use.
3. If this code posts on only one sample or QC level, the sample may have a low Total Protein concentration.	3. Run Total Protein on fluid.
4. If this code occurs for all samples, verify that WF maintenance was performed.	4. a. Replace the IWF reservoir and tip. b. Replace the WF METERING TUBING if necessary.
5. If this code occurs for all samples, verify that the LOT of IWF in use was the LOT used to calibrate the slide LOT.	5. Calibrate slide LOT with the LOT of IWF in use.
6. If this code occurs for all samples, verify that the calibrator kit LOT number was properly selected when the LOT of slides in use was calibrated.	6. Check that the calibrator kit LOT is available on the Calibration programming screen. a. Reload the most recent Assay Data Disk if necessary. b. Recalibrate all IR assays.

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Pub. No.: J56080EN