Ortho Clinical Diagnostics

PART OF THE *Johnson&Johnson* FAMILY OF COMPANIES

January 25, 2016

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Increase in Condition Codes using VITROS® 4600 Chemistry System Software Version 3.2.1

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

This is to inform you of an Important Product Correction Notification involving the following:

VITROS® Product	Product Code	Software Version	Unique Device Identifier No.
VITROS® 4600 Chemistry System	6802445	Version 3.2.1	10758750012343

Ortho Clinical Diagnostics, Inc. (Ortho) initiated this Important Product Correction Notification due to a software anomaly that may *potentially* cause an increase in condition codes on VITROS® 4600 Systems. Customers reported an increase in TM5-4FB condition codes following the installation of Software Version 3.2.1. The purpose of this notification is to inform you of the anomaly and provide the Release Notes prior to the availability of the new software.

The TM5-4FB condition code (*uIA METERING Aspirate Cuvette %s –Bubble*) indicates the potential presence of air bubbles during fluid aspiration from a cuvette. Due to the anomaly, this code may occur even if bubbles are not present. The increase in condition codes associated with Software Version 3.2.1 only occurs during fluid aspiration from a cuvette using a MicroTip (not a VersaTip). Therefore this issue does not affect MicroSlide processing.

Impact to Result

When a TM5-4FB condition code initially occurs as an "Attention" code, the VITROS® System suppresses the result and when possible, automatically reprocesses the test.

If the TM5-4FB condition code occurs more than once in succession, the system will post a "Malfunction" code indicating that operator intervention is required (e.g., Initialization to re-enable the uIA Metering subsystem).

All results obtained are valid providing quality control results were within acceptable limits.

Resolution

VITROS® 4600 System Software Version 3.2.2 [Modification (MOD) No. A5] will contain the resolution to help prevent false occurrences of TM5-4FB condition codes. To help prevent potential occurrences, we advise that you install Software Version 3.2.2 even if you have not experienced an increase in TM5-4FB condition codes.

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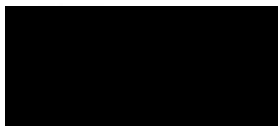
Software Prerequisite

Software Version 3.2.1 must be installed prior to loading Version 3.2.2. The current version number of software appears in the upper right corner of the analyzer screen. If you do not have Software Version 3.2.1, please contact our Technical Solutions Center representatives to obtain the appropriate version of software.

Actions Required from You

1. Install Software Version 3.2.2 upon availability

   ➢ <u>Automatic download</u> for e-Connected systems is expected to be available the week of February 1, 2016

   ➢ Software kits will be issued upon availability

2. Follow the instructions provided in the condition code text if you experience TM5-4FB condition codes.

3. Post this notification near your VITROS® System or store with your user documentation until the Software Version 3.2.2 is installed.

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,

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Lee, Ching Hwee
Senior Regulatory Affairs Specialist

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Increase in Condition Codes using VITROS® 4600 Chemistry System Software Version 3.2.1