Ortho Clinical Diagnostics

July xx, 2014

URGENT FIELD SAFETY NOTICE

Anomaly Using Software Version 3.0 & Below on
VITROS® 3600 Immunodiagnostic Systems, VITROS® 4600 Chemistry Systems &
VITROS® 5600 Integrated Systems

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this communication is to inform you that Ortho Clinical Diagnostics (OCD) has identified an anomaly with VITROS® System Software Version 3.0 and below. Internal testing confirmed that under very *specific* conditions, incorrect patient demographics were associated with a sample identification (ID) number. The following System Software is affected:

VITROS® System	System Product Code	Affected VITROS® Software Version
VITROS® 3600 Immunodiagnostic System	6802783	Version 3.0 & Below
VITROS® 4600 Chemistry System	6802445	
VITROS® 5600 Integrated System	6802413	
Note: *The potential for the anomaly to occur exists in all current and previous versions of VITROS® Software.*		

Description of Anomaly

Our internal investigation confirmed that under specific circumstances (described on page 3), patient demographics may be incorrectly associated with a sample ID number. This issue may occur when Condition Code PY1-075 is generated for a sample ID and the operator does not follow the instructions provided below in the Condition Review in V-DOCs.

PY1-075: Unable to find matching program: ID: %s, Tray %s, Cup %d

Operator Actions	
Possible Causes	**Things to do**
1). Samples incorrectly placed on tray.	1). **Move the sample to a tray location that is not being used by another sample program.**

If the operator does not follow the instructions and manually programs that sample in the Tray/Cup listed on the Condition Code screen, the intended assays will be processed. However, the patient demographic data associated with that sample's barcode may be incorrect.

IMPORTANT TO NOTE: If patient demographic data are not used on your VITROS® System (i.e., entered via the Sample Programming screen or downloaded by the LIS), the anomaly **will not occur**.

Actions Required

- If a PY1-075 condition code occurs on your VITROS® 3600, 4600 or 5600 System during sample processing, move the sample to different cup and position as stated in V-DOCs.
- Complete and return the Confirmation of Receipt form no later than **July 16, 2014**.
- Post this notification by each VITROS® System in your facility or with the user documentation.
- Please contact Ortho Clinical Diagnostics if you become aware of an impact to patient safety caused by this anomaly.

Resolution

The resolution to this software anomaly will be contained in the next software version that is scheduled to be released within a few months. Until the new version of software is installed on your VITROS® System, if a PY1-075 condition code occurs when processing a sample, move the sample to different cup and position as stated in your user documentation.

We apologize for the inconvenience this may cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number.*

Sincerely,

Insert appropriate name
Insert appropriate title

Questions and Answers

1. What specific sequence of events causes the anomaly to occur?

For incorrect patient demographic data to be associated with a Sample ID, the following specific sequence of events must occur.

A. Sample Programming assigned to a specific Tray/Cup location (e.g., Tray 10 /Cup 5) for Patient Sample #1 is **pending** (i.e., Sample Processing incomplete)

B. A sample associated with Patient #2 is placed in the exact same position (Tray 10/Cup 5) as the **pending** sample programming associated for Patient #1.

C. The barcode on the sample associated with Patient # 2 in Tray 10/Cup 5 is scanned and Condition Code PY1-075 is generated by the VITROS® System.
(This Condition Code is generated because the Sample ID scanned (sample for Patient # 2) does not match the Sample ID previously programmed (sample for Patient # 1) for the same Tray/Cup location.

D. If the sample is **not** moved to a different tray/cup location and the operator manually programs the sample for Patient # 2, the anomaly may occur.

2. What VITROS® Systems are affected by this anomaly?

This anomaly only affects VITROS® 3600, 4600, and/or 5600 Systems. The potential for the anomaly to occur exists in all current and previous versions of VITROS® Software.

No other VITROS® Systems are affected.

3. What if my VITROS® System is configured with an enGen™ Laboratory Automation System?

The anomaly does not affect the enGen™ Laboratory Automation System. Instructions provided in this notification are specific to the VITROS® System. Additional actions are not required for other components of your enGen™ Laboratory Automation System.

4. When will this anomaly be resolved?

This anomaly will be resolved in the next version of software scheduled to be released within a few months.

Confirmation of Receipt – Response Required

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Please return completed form by fax or scan to PDF and email so that we can complete our records no later than: xx-July-2014

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

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2014-191_EU) regarding specific conditions, in which incorrect patient demographics may be associated with a sample identification (ID) number. I understand that if a PY1-075 condition code occurs on my VITROS® 3600, 4600 or 5600 System during sample processing, I am required to move the sample to different cup and position.

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: _____