Ortho Clinical Diagnostics
a Johnson & Johnson company

May xx, 2009

URGENT FIELD SAFETY ACTION

VITROS® 3600 Immunodiagnostic System
VITROS® 5600 Integrated System
Configuration of Display/Report using Software Versions 1.2.4 & Below

Dear Customer,

Ortho Clinical Diagnostics (OCD) has received one customer complaint of a biased Glucose result on a VITROS® 5600 Integrated System. Our investigation of the complaint determined that under a very specific set of circumstances, when the Display/Report screen is configured by the operator in the following sequence, an erroneous result could be generated by the VITROS® 3600 Immunodiagnostic System or VITROS® 5600 Integrated System.

All of the following five steps must occur in order to cause the issue to occur:

1. Operator configures the order of appearance of assays in the Assay Menu and excludes a particular body fluid for that assay.
   (*For example: GLU includes Serum and Plasma but Urine GLU is excluded*) **AND**
2. Operator reconfigures the Display/Report screen and moves a new assay target to a blank location that was previously assigned to an excluded assay target
   (*For example: Urine GLU is replaced with BUN*) **AND**
3. Both assays (*GLU & BUN*) must be programmed to process the same sample **AND**
4. Both assays (*GLU & BUN*) must be of the same technology type (e.g., *MicroSlide*) and have a compatible calibration type (e.g., *Colorimetric*) **AND**
5. Both assays (*GLU & BUN*) must have a common Generation number (or Lot # for MicroWell assays) supported on the Assay Data Diskette.

OCD will implement a software change in the near future to prevent this anomaly. In the interim, please restore default settings on your VITROS® 3600 Immunodiagnostic System or VITROS® 5600 Integrated System for Display/Reports as described below.

Please do the following:

- Restore default settings for your VITROS 3600 System or VITROS 5600 System by:
  1. On the Systems Status screen, select *Set Access Level* and enter the access code
  2. In the Options & Configuration screen, select *Configure System*
  3. Select *Display/Report*
  4. Select *Restore Defaults*
  5. Select *Save*
  6. Touch *Return/Cancel* to return to the Options & Configuration screen

NOTE: You may observe SYJ-004 condition codes while restoring the default settings. No action is required. We advise that you create a new back up diskette after restoring the default settings.

- If you have not configured the Display/Report feature, maintain the default settings until further notice.
- Complete and return the attached Confirmation of Receipt Form upon receipt of this notification. Please return this form no later than **June xx, 2009.**

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

Sincerely,

insert appropriate name
insert appropriate title

Questions and Answers

1. **How can I determine if this issue has occurred on my VITROS 3600 System or VITROS 5600 System?**

   All five steps described on page one must occur in order to cause this issue. *If* it had occurred on your system:

   - One or both of the affected assays would have had an 'LS' lot switch code on the Laboratory Report when an actual lot switch did not occur for either assay.

2. **What systems and assays are affected by this issue?**

   This issue can occur on either a VITROS 3600 System or a VITROS 5600 System and can affect MicroSlide, MicroTip and/or MicroWell assays.

3. **Do I need to restore default settings for the Assay Menu configuration?**

   No, there is no impact to the Assay Menu configuration settings. It is not required to modify your current settings.

4. **How do I determine what type of calibration type is used for an assay?**

   Refer to the *Calibration* section of the Instructions For Use documents to determine the calibration model for an assay.

5. **Does modifying the default settings for the Display/Reports affect my Laboratory Information System?**

   The order in which result records are transmitted to the LIS is dependent upon the Display/Report settings. The Display/Report settings will return to the default order when the default settings are restored.

6. **How often did this issue occur?**

   To date, Ortho Clinical Diagnostics has only received one report of this occurrence. We are continuing to monitor systems that are e-connected.

7. **What are consequences if I do not restore the default settings on my system?**

   An erroneous result could be generated by the VITROS® 3600 System or VITROS® 5600 System under a very specific set of circumstances (defined on the previous page) when the Display/Report screen is configured by the operator. If you have reconfigured the Display/Report settings on your system, you are required to restore the default settings.

8. **When will this issue be resolved?**

   We will implement a software change in the near future to prevent future occurrences of this anomaly. In the next few weeks, you will also be sent a Technical Bulletin with this information to add to your appropriate user documentation.

Confirmation of Receipt - Important Response Required

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So that we can complete our records, please return this form to us no later than **May xx, 2009.**

FAX TO: ***insert appropriate name***
FAX TO: ***insert appropriate number***
Section I - Confirmation

Section I– Confirmation

I received the Urgent Product Correction Notification (CL09-194), and understand that I must:

- Restore the default settings for Display/Reports feature, if configured on my VITROS 3600 System or VITROS 5600 System

- Maintain the default settings if I have not configured the Display/Report feature on my VITROS 3600 System or VITROS 5600 System.

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

Your Name: _____ Job Title (optional): _____

Signed*: _____ Date: _____

Fax Number: _____ Telephone Number: _____

Institution: _____

Your comments are always welcome:

_____

Section II – Verify Your Name and Address:

Please complete this section if you would like update your address:

Institution / Contact Name: _____

Address: _____

City: _____ **State:** _____ **Zip/ Code:** _____

Telephone: _____