

July XX, 2010

## Urgent Field Safety Notice

### VITROS<sup>®</sup> 5600 Integrated System Software Version 1.4 and below VITROS<sup>®</sup> 3600 Immunodiagnostic System Software Version 1.4 and below MicroWell and/or MicroTip Reagent Management

Dear Customer,

The purpose of this notification is to inform you of two scenarios regarding MicroWell and/or MicroTip Reagent Management on the VITROS<sup>®</sup> 5600 Integrated System and VITROS<sup>®</sup> 3600 Immunodiagnostic System in which the MicroWell and/or MicroTip Reagent inventory may not be properly updated. When these scenarios occur, it is possible for the VITROS<sup>®</sup> 5600 Integrated System and VITROS<sup>®</sup> 3600 Immunodiagnostic System to process results from a Reagent Pack other than the intended Reagent Pack without alerting the user.

If the following two scenarios summarized in this letter occur, they can potentially result in misidentified MicroWell and/or MicroTip Reagent Packs and incorrect results or “No Result” being reported by the system:

- **Two Simultaneous Reagent Supply Scans:** a specific series of events that causes two reagent supply scans to occur simultaneously. (See Scenario One below).
- **Loading Reagent Packs when the LED Indicator is not lit:** a reagent supply door is opened when the associated LED indicator light is not lit and the system is scanning a pack within the MicroWell and/or MicroTip Reagent Supply. (See Scenario Two below).

#### **Scenario One: Two Simultaneous Reagent Supply Scans**

It is possible for the VITROS<sup>®</sup> 5600 Integrated System and VITROS<sup>®</sup> 3600 Immunodiagnostic System to perform two scans simultaneously if the following sequence of events occurs:

1. The MicroWell and/or MicroTip Reagent Supply contents are being scanned as part of the system initialization, **and**
2. The initialization fails due to a mechanical error before the scan is complete, **and**
3. The system displays the “Not Ready” message in the top left corner of the Status Console, **and**
4. The initialization button is touched within ten seconds following the display of the “Not Ready” message.

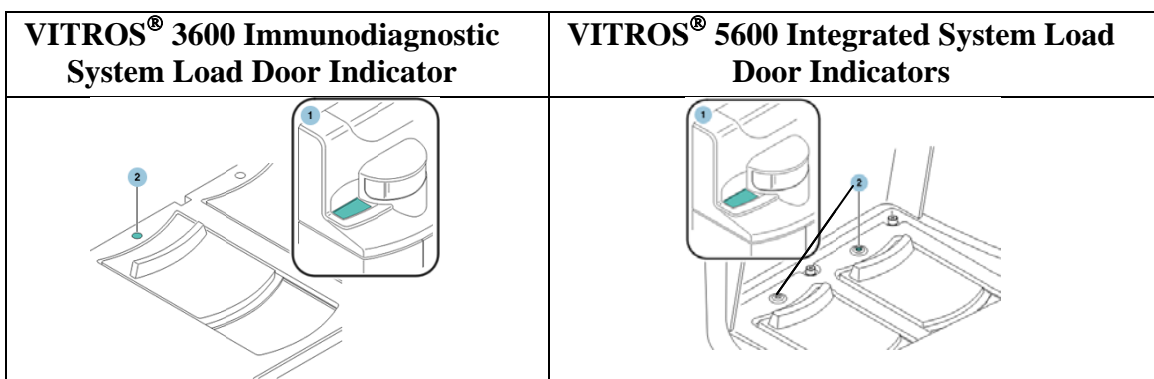
The second initialization starts a second scan of the MicroWell and/or MicroTip Reagent Supply. Upon scanning of the first two reagent packs, two PVD-019 condition codes may occur. The condition code text will indicate reagent packs to be removed from the Reagent Supply. For example, “Duplicate sequence number. Remove TSH, Supply 4 Slot 2”.

These two Reagent packs may also be designated as “Dup Seq” in the Reagent Management Screen status view. **Any additional reagent packs remaining in the affected Reagent Supply could also be misidentified without the PVD-019 condition code or “Dup Seq” notification.**

To prevent this occurrence if a system initialization fails, the Initialize button on the Condition Review screen must **not** be touched for **at least 15 seconds** after the “Not Ready” message is displayed in the top left corner of the Status Console. Following this instruction will help to ensure completion of any inventory scan of the MicroWell and/or MicroTip Reagent Supply that is already in progress following the first initialization.

**Scenario Two: Loading Reagent Packs when the LED Indicator is not lit**

Reagent Packs may be misidentified when the Reagent Supply load door<sup>1</sup> is opened before the green LED indicator lights<sup>2</sup> for the MicroTip and/or Microwell Reagent Supplies.



This scenario is caused by the following events:

1. The MicroWell and/or MicroTip Reagent Supply load door is opened before the green LED Indicator lights, and while a reagent supply scan is occurring, **and**
2. The Reagent Supply Ring is manually moved so that the position that was just scanned is moved to the load door position, **and**
3. The MicroWell or MicroTip Reagent Pack in the load door position is removed and another pack is loaded in the same position.

As a result of these events, one Reagent Pack in the affected Reagent Supply could be misidentified if the second reagent pack loaded is different from the original reagent pack that was scanned. To prevent this occurrence, do not open the reagent supply load door until the green LED indicator lights (as per V-Docs procedures). This indicates the Reagent Supply Ring is in position for loading.

***Please do the following:***

- If a system initialization fails, wait at **least 15 seconds** after the “Not Ready” message is displayed before touching the Initialize button on the Condition Review screen.
- Before loading reagent packs, wait for the Reagent Supply green LED Indicator on the load door to light prior to opening the Reagent Supply Load door.
- Display this communication near the system to ensure compliance by all operators of the VITROS<sup>®</sup> 5600 Integrated System or VITROS<sup>®</sup> 3600 Immunodiagnostic System.
- Complete and return the attached Confirmation of Receipt Form by August **XX**, 2010.
- Forward this information if you have distributed this product outside of your facility.

Ortho Clinical Diagnostics will implement a software change in the near future to resolve these issues. We apologize for any inconvenience this may cause your laboratory. We have anticipated some questions you may have in the Question and Answer section. If you have any additional questions about this notification or are aware of occurrences of these issues, please call our Customer Technical Services *Insert Appropriate phone number*.

Sincerely,

*Insert Appropriate Name and Title*

## Questions and Answers

### 1. What assays and systems are affected by these scenarios?

This issue can occur with MicroTip and MicroWell assays on a VITROS<sup>®</sup> 5600 Integrated System or with MicroWell assays on a VITROS<sup>®</sup> 3600 Immunodiagnostic System.

### 2. Do I need to confirm every MicroTip or MicroWell reagent pack is accurately inventoried on the Reagent Management screen?

No, both the VITROS<sup>®</sup> 5600 Integrated System and VITROS<sup>®</sup> 3600 Immunodiagnostic System track on-board inventory accurately. However, it is necessary to follow the Instructions in this Customer Letter CL10-231a to prevent potential occurrences of misidentified reagent packs.

### 3. When will this issue be resolved?

We will implement a software change in the near future to prevent future occurrences of this anomaly.

### 4. What actions should I take if I suspect that the inventory has not been properly updated after a reagent pack is loaded?

To update the MicroWell and/or MicroTip Reagent supply inventory:

Touch Diagnostics > MEDs > uIA Reagent Supply. Open and close the Load Door for Reagent Supply 3 and 4. Then touch Return until you return to the System Status screen.

This causes every MicroWell and MicroTip Reagent Pack to be scanned and inventoried properly. Be advised that reagents that were manually loaded will need to be reloaded.

### 5. What actions should I take regarding previously reported results?

If you suspect that either of these issues has occurred at your facility, you should consult with your Laboratory Medical Director and requesting physician to resolve any concerns you may have regarding previously reported patient results.

### 6. What Software Versions are affected?

Software Version 1.4 and below are affected for VITROS<sup>®</sup> 5600 Integrated System.

Software Version 1.4 and below are affected for VITROS<sup>®</sup> 3600 Immunodiagnostic System.

### 7. Can a MicroWell Reagent Pack be misidentified as a MicroTip Reagent Pack, and can a MicroTip Reagent Pack be misidentified as a MicroWell Reagent Pack?

No, a MicroWell Reagent Pack can only be misidentified as another MicroWell Reagent Pack. A MicroTip Reagent Pack can only be misidentified as another MicroTip Reagent Pack.

**Confirmation of Receipt Important Response Required**

**Urgent Field Safety Notice**

**VITROS® 5600 Integrated System Software Version 1.4 and below  
VITROS® 3600 Immunodiagnostic System Software Version 1.4 and below  
MicroWell and/or MicroTip Management**

So that we can complete our records, please return this form to us no later than August **XX**, 2010

**FAX TO:** *Insert Appropriate Name*  
**FAX:** *Insert Appropriate Fax Number*

**Section I – Confirmation**

I received Important Product Correction Notification (CL10-231a) and understand that I must follow the Instructions for MicroTip and MicroWell Reagent Pack Reagent Management included with this communication. These instructions are intended to prevent a Reagent Pack from being misidentified **if** two reagent supply scans occur simultaneously or a reagent supply door is opened when the green LED indicator is not lit while the system is scanning a pack within the MicroWell and/or MicroTip Reagent Supply. Additionally, I am not aware of occurrences of either of these issues at my facility, but will notify OCD Customer Technical Services at *insert appropriate phone number* if I become aware of an occurrence.

Your Name: \_\_\_\_\_ Job Title (optional): \_\_\_\_\_  
Signed\*: \_\_\_\_\_ Date: \_\_\_\_\_  
Fax Number: \_\_\_\_\_ Telephone Number: \_\_\_\_\_  
J Number: \_\_\_\_\_ Institution Name: \_\_\_\_\_

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

*Your comments are always welcome:*

\_\_\_\_\_  
\_\_\_\_\_

**Section II – Your Name and Address**

Verify your name and mailing address:

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State/Province: \_\_\_\_\_ Zip/Postal Code: \_\_\_\_\_  
Telephone: \_\_\_\_\_ FAX: \_\_\_\_\_