

October **XX**, 2010

URGENT FIELD SAFETY NOTICE

VITROS[®] 5600 Integrated System Software Version 1.5 and below VITROS[®] 5,1 FS Chemistry System Software Version 2.5 and below MicroSlide Reagent Management

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you of an issue regarding MicroSlide Reagent Management on the VITROS[®] 5600 Integrated System (Product Code 6802413) and VITROS[®] 5,1 FS Chemistry System (Product Code 6801375) using the manual cartridge load feature. There have been rare occurrences where a MicroSlide cartridge is misidentified after entering MicroSlide cartridge lot information in the “Manually Load Cart” dialog. When this issue occurs, it is possible for the VITROS[®] 5600 Integrated System and VITROS[®] 5,1 FS Chemistry System to process results from a cartridge other than the intended cartridge, potentially leading to erroneous patient results.

This anomaly occurs when a MicroSlide cartridge is manually identified, but not loaded in the slide supply slot presented. The slot presented may contain a MicroSlide cartridge that is not empty. This scenario of the system presenting a slot with a cartridge that is not empty, is not described in the V-Docs instructions for manually loading MicroSlide cartridges.

For this issue to occur, the following five steps must occur in sequence:

1. In the reagent “Load Unload” process, the user replaces an empty cartridge with a cartridge of the same analyte type, generation and lot number, **and**
2. The reagent “Load Unload” session is completed by the user selecting “Done” in the “Load/Unload Reagents” dialog, **and**
3. The user selects “Manual Load” for the same Reagent Supply to identify and load an additional MicroSlide cartridge of a different analyte type, and the cartridge loaded in step 1 has a status of “Inv??” on the Reagent Management screen, **and**,
4. The slot presented for the cartridge manually identified in step 3 is the same slot that contains the cartridge loaded in step 1, **and**
5. The Slide Supply Load Door is opened; but the cartridge presented in the slot is not removed, the manually identified cartridge is not loaded and then the Slide Supply Load Door is closed.

The cartridge that was not removed from the Slide Supply in step 5 will be assigned with the cartridge lot information that was manually entered in step 3; resulting in that MicroSlide cartridge being misidentified.

This issue occurs under rare conditions; however, if you suspect this issue may apply to 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. Please refer to the Question and Answers Section for information regarding VITROS[®] Chemistry Products, including high risk VITROS[®] Chemistry Products, that could be affected if this issue occurred.

URGENT FIELD SAFETY NOTICE

VITROS[®] 5600 Integrated System Software Version 1.5 and below
VITROS[®] 5,1 FS Chemistry System Software Version 2.5 and below
MicroSlide Reagent Management

Please do the following:

- Follow the Revisions to the Load MicroSlide Cartridges Procedures **found on page three** of this communication to ensure that a MicroSlide cartridge is identified correctly during the manual load process.
- Complete and return the attached Confirmation of Receipt Form by October **XX**, 2010.
- Display this communication near the VITROS[®] System to ensure compliance by all operators of the VITROS[®] 5600 Integrated System or VITROS[®] 5,1 FS Chemistry System.
- Forward this information if you have distributed this product outside of your facility.

Ortho Clinical Diagnostics (OCD) will implement a software change in the near future to mitigate this anomaly. We apologize for any inconvenience this may cause your laboratory. If you have questions about this notification, please call our Customer Technical Services at ***Insert Appropriate phone number.***

Sincerely,

Insert Appropriate Name and Title

Revisions to the Load MicroSlide Cartridges Procedures

When you load a MicroSlide cartridge, the system presents a slot in either Slide Supply 1 or Slide Supply 2 to receive the cartridge. **If there is a cartridge in the slot presented, remove it.**

- If the cartridge that you remove is empty, discard it.
- If the cartridge that you remove contains MicroSlides that can still be used on the system, load the cartridge in a subsequent Reagent Management load session or store the cartridge appropriately.

During the manual load process, once you open the Slide Supply door, you must place the cartridge that you have identified in the “Manually Load Cart” dialog into the slot presented. If a cartridge is already present in the slot, remove it and place the new cartridge that you have identified into the presented slot.

The following V-Docs procedures require the same revision:

- VITROS[®] 5,1 FS Chemistry System: Loading Slide Cartridges procedure (Step 9)
- VITROS[®] 5600 Integrated System: Slide Cartridge Loading procedure (Step 9)
- VITROS[®] 5600 Integrated System: Manual Slide Cartridge Loading procedure (Step 8)

Revisions to Step 9 and Step 8:

Open the LOAD DOOR for the appropriate SLIDE SUPPLY. If there is a slide cartridge occupying the slot, remove it. If the cartridge that you have removed is empty, discard it. If the cartridge contains MicroSlides that can still be used on the system, load this cartridge in a subsequent Reagent Management load session or store the cartridge appropriately.

Important: During the manual load process, once you open the Slide Supply door, you must place the cartridge that you have identified in the “Manually Load Cart” dialog into the presented Slide Supply slot. Failure to do so may result in tests being performed with slides from an incorrect cartridge, potentially leading to erroneous patient results.

URGENT FIELD SAFETY NOTICE

VITROS[®] 5600 Integrated System Software Version 1.5 and below
VITROS[®] 5,1 FS Chemistry System Software Version 2.5 and below
MicroSlide Reagent Management

Questions and Answers

1. What systems and assays are affected by this issue?

This issue can occur on either a VITROS[®] 5600 Integrated System or VITROS[®] 5,1 FS Chemistry System and will affect only MicroSlide assays.

2. What Software Versions are affected?

Software Version 1.5 and below are affected for VITROS[®] 5600 Integrated System.
Software Version 2.5 and below are affected for VITROS[®] 5,1 FS Chemistry System.

3. What high risk VITROS[®] Chemistry Products could produce erroneous, yet credible results if this issue occurred at my facility?

All VITROS[®] Chemistry Products Slides could be affected. Examples of high risk VITROS[®] Chemistry Products that produced erroneous, yet credible results while investigating this issue include:

- VITROS[®] ACET Slides
- VITROS[®] AMON Slides
- VITROS[®] BuBc Slides
- VITROS[®] Ca Slides
- VITROS[®] CKMB Slides
- VITROS[®] CRBM Slides
- VITROS[®] DGXN Slides
- VITROS[®] Fe Slides
- VITROS[®] GLU Slides
- VITROS[®] LAC Slides
- VITROS[®] Li Slides
- VITROS[®] PHBR Slides
- VITROS[®] SALI Slides

4. What actions should I take regarding previously reported results?

This issue occurs under rare conditions; however, if you suspect this issue may apply to 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.

5. When will this issue be resolved?

In the near future, OCD will release a software update that will, under certain circumstances, prevent a Slide Supply Slot containing a full cartridge from being presented when “Manual Load” is selected. Specifically, Slide Supply slots containing a just-loaded cartridge with a status of “Inv??” will not be available for loading of additional cartridges. However, any slide cartridge that may already be contained in the slot presented must be removed in order to complete the manual load.

URGENT FIELD SAFETY NOTICE

VITROS[®] 5600 Integrated System Software Version 1.5 and below
VITROS[®] 5,1 FS Chemistry System Software Version 2.5 and below
MicroSlide Reagent Management