

March xx, 2015

URGENT FIELD SAFETY NOTICE **Anomaly using Software Version 2.8 & Below on** **VITROS® 5,1 FS Chemistry Systems**

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you of an Urgent Field Safety Notice involving the following:

VITROS® Product	Affected Software Versions	Product Code	GTIN*
VITROS® 5,1 FS Chemistry System	Version 2.8 & Below	6801375	10758750001132
		6801890	10758750001644

*Global Trade Item Number (GTIN) represents the Unique Device Identifier (UDI).

Description of Anomaly

Ortho-Clinical Diagnostics, Inc. (OCD) has confirmed two instances where a VITROS® MicroSlide cartridge was misidentified. Both instances occurred when an operator accessed Slide Supply 1 (SS1) before the green indicator light was illuminated and subsequently proceeded to load a slide cartridge into Slide Supply 2. In each occurrence, the loaded cartridge in Slide Supply 2 was misidentified. Refer to the Question and Answer section on Page 3 for a detailed description and additional information.

Impact to Results

If this anomaly occurs, it is possible for VITROS® 5,1 FS Systems to process samples with a cartridge other than the intended cartridge, potentially leading to erroneous patient results. If this anomaly occurred previously, an indication would be a series of results that were similar across multiple samples (i.e., results could be believable or outside of the Reportable Range for the intended assay). Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Required Actions

- Do not open either Slide Supply load door before the green indicator light is illuminated.
- Do not load MicroSlide cartridges unless the “Load/Unload Reagents” dialog box is displayed.
- If you inadvertently access a Slide Supply load door before the green indicator light is illuminated and the system generates a TAS-70E or TAS-20E condition code, do the following:
 - ✓ Open and close **both** Slide Supply doors (Slide Supply #1 & 2).
 - ✓ Avoid removing or adding cartridges.
 - ✓ Initialize the system.
 - ✓ If any cartridges have been manually loaded, reload them by following “Manually Loading Slide Cartridges” procedures in V-docs.
- Complete and return the Confirmation of Receipt form no later than **March xx, 2015.**

Resolution

The resolution to this anomaly will be contained in the next version of software currently under development. We will issue a follow up notification upon the software's availability.

In the interim, if an operator inadvertently accesses a Slide Supply load door before the green indicator light is illuminated and the system generates a TAS-70E or TAS-20E condition code (SLIDE SUPPLY 1 DOOR is OPEN or SLIDE SUPPLY 2 DOOR is OPEN), the operator must open and close **both** Slide Supply doors (Slide Supply #1 & 2), not remove or add any cartridges, and initialize the system. This will cause the system software to scan all slots of both Slide Supplies in order to properly identify the contents.

Rate of Occurrence

Analysis of e-Connectivity[®] data suggests the probability of occurrence of this anomaly to be approximately 1 in 400,000 opportunities.

We apologize for the inconvenience this may cause your laboratory. We have anticipated some questions you may have in the following Question and Answer 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 caused this anomaly to occur?

The following is an *example* of how this anomaly occurred:

- The Slide Supply 1 (SS1) access door was opened before the green indicator light was illuminated, which generated a malfunction code of TAS-70E (SLIDE SUPPLY 1 DOOR is OPEN).
- At that time, Slot #9, located at the load position in Slide Supply 2 (SS2), contained an empty cartridge.
- The Operator started to initialize the analyzer, but SS2 cartridge rotor did not initialize since an error occurred in SS1. The green indicator light for SS2 did not turn off as expected, and the system continued to move the SS2 rotor.
- Slot #4 in SS2 contained a cartridge of VITROS[®] Fe Slides that was accessible, but was not fully aligned with the load door or lifted to the load position.
- The Operator removed the VITROS[®] Fe Slides cartridge, which was not empty, from Slot #4 of SS2 and replaced it with a cartridge of VITROS[®] ALT Slides. The system did not recognize that the VITROS[®] Fe Slides cartridge was removed, which caused the VITROS[®] 5,1 FS System to process samples with VITROS[®] ALT Slides and incorrectly report them as samples processed with VITROS[®] Fe Slides.

2. Are immediate actions required?

Yes. Do not load reagents unless the green indication light is illuminated and the “Load/Unload Reagents” dialog box is displayed. Until the new software is installed, if you inadvertently access a Slide Supply load door before the green indicator light is illuminated and the system generates a TAS-70E or TAS-20E condition code, please do the following:

- ✓ Open and close **both** Slide Supply doors (Slide Supply # 1 & 2).
- ✓ Avoid removing or adding cartridges.
- ✓ Initialize the system.
- ✓ If any cartridges were previously manually identified, reload them by following manual load procedures.

3. Which VITROS[®] Systems are affected by this anomaly?

This anomaly only affects the results generated by VITROS[®] 5,1 FS Systems.

VITROS[®] 4600 and 5600 Systems contain software algorithms that will detect the issue. If the anomaly occurs, slides would still be processed; however, the software would suppress the results and generate P01-102 condition codes.

VITROS[®] 250/350 System software does not allow the operator to manually open the Slide Supply load doors.

Questions and Answers (continued)

4. Which Slide Supplies are affected?

When Slide Supply 1 is accessed before the green indicator light is illuminated, the anomaly will only affect the first cartridge loaded in Slide Supply 2. Other Reagent supplies are not affected. To reinforce consistency in system operation, OCD is requesting that the operator perform the required actions indicated on page 1 when either Slide Supply load door is opened prior to illumination of the green indicator light.

5. Which VITROS[®] Slides can be stored in Slide Supply 2?

The following types of VITROS[®] Slides are stored in Slide Supply 2:

ACET	ALKP	AST	CKMB	Fe	LAC	PROT
AcP	ALT	CHE	CREA	GGT	LDH	SALI
ALC	AMON	CK	ECO ₂	GLU	Li	THEO

6. How can I determine if the anomaly occurred on my VITROS[®] 5,1 FS System?

There is no definitive way to determine if this anomaly previously occurred. However, an indication would be a series of results that were similar across multiple samples (i.e., results could be believable or outside of the Reportable Range for that assay).

7. What is OCD doing to resolve this issue?

This anomaly will be resolved in a future software version that is scheduled to be released within a few months. We will also issue a notification upon software availability.

In the interim, we will issue a Technical Bulletin containing the information in this notification.