Ortho Clinical Diagnostics	**URGENT FIELD SAFETY NOTICE** **Temperature Monitoring Anomaly on VITROS® Systems using Software Version 3.2 and Below** **Immediate Action Required**

Date Issued

November xx, 2015

Affected Products

Product Name	Product Code	Unique Device Identifier No.
VITROS® 3600 System Software Version 3.2 & Below	6802866	10758750009930
VITROS® 5600 System Software Version 3.2 & Below	6802864	10758750009916

Issue Explanation

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics (Ortho) initiated this Urgent Field Safety Notice due to a software anomaly in which the temperature in the Well Wash module may be out of range without notification to the operator.

Temperature monitoring is performed by the VITROS® System for each subsystem (i.e., MicroSlide, MicroTip and MicroWell). Our investigation confirmed that under very specific conditions (described on page 2), the temperature for the Well Wash module may be out of range without alerting the operator. Refer to the Question and Answer section for detailed information.

Impact to Results

If the anomaly occurs, it is possible for the VITROS® System to process samples outside of the proper temperature range, potentially leading to a biased patient result. The results will not be flagged with a 'WT' (Wash Temperature) result code. Refer to the enclosure for the potential bias that may occur. Events that occurred prior to this communication are not easily identifiable; thus, a review of previous results is impractical. Therefore, discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Required Actions

- Verify that the temperature for the MicroWell subsystem is within proper temperature range prior to sample processing by following the instructions provided.
- If a temperature is out of range and the status bar indicates that the system is "*Ready*" or the temperature icon is NOT present, contact our Technical Solutions Center.
- Post this notification by the affected VITROS® System(s) or with your user documentation.
- Complete and return the Confirmation of Receipt form by **November xx, 2015**.

Resolution

The resolution related to the temperature monitoring software anomaly will be contained in the next version of software currently under development. Until the new software is installed, follow the enclosed instructions.

In addition, there will be a modification to the temperature monitoring device for the Microwell subsystem. An Ortho-trained service representative will contact you to schedule the installation upon availability.

Contact Information

If you have any questions, contact our Technical Solutions Center at insert number.

Insert signature if appropriate

Enclosures:

1. Confirmation of Receipt form
2. Instructions to Verify Temperature
3. Impact to Results

Questions and Answers

1. **How is the VITROS® System designed to monitor temperature?**

   Incubator and fluid temperatures are monitored by the VITROS® System for each subsystem (i.e., MicroSlide, MicroTip and MicroWell). If a temperature is out of range, the system will post a condition code to alert the operator, and a temperature icon will appear on the Status bar. The results will be flagged with "IT" (incubator temperature) or "WT" (well wash temperature) for results produced from that module. Sample metering for the affected subsystem will be discontinued.

2. **What subsystems are affected by this issue?**

   Our investigation determined that this issue predominantly affects the MicroWell subsystem. The temperature monitoring device (i.e., Thermistor) is located within the MicroWell Wash Assembly that mounts on the movable Well Wash arm. The MicroWell Wash Assembly is the only module in which the wires are continually moving and flexing during normal processing. Over time, the Thermistor wires may degrade resulting in an electrical short/open circuit, causing the intermittent issue that may not be detected due to the software anomaly.

   The MicroSlide and MicroTip subsystems utilize a solid mounting of the Thermistor. If there is an issue with the Thermistor, it would not be intermittent, and therefore, it would be detected by the software.

3. **What causes the anomaly to occur?**

   The anomaly is associated with an intermittent failure due to an electrical short/open circuit in the MicroWell Wash Assembly.

   The resolution will be contained in the next version of software currently under development. In addition, there will be a modification to the MicroWell Wash Assembly that will help to decrease the potential for the electrical short or open circuit to occur.

4. **How often does this issue occur?**

   Analysis of e-Connectivity® data estimates the probability of affected results, to be approximately 1 out of 200,000 results using the MicroWell subsystem (approximately 0.0005%). The probability for the other sub-systems is less than 1 in 14 million.

5. **What is the impact to MicroWell Assay results if my VITROS® System was out of temperature range?**

   If the issue occurs, samples will not be properly flagged with a 'WT' result code (Wash Temperature) and the results may be biased.

   Ortho conducted testing for selected temperature-sensitive assays that use the MicroWell module. Samples were tested at nominal temperature (37°C) and at ambient room temperature (~25°C). A summary of the data is provided in the enclosure.

Questions and Answers (continued)

6. Are other VITROS® Systems affected by this issue?

This issue predominantly affects VITROS® 3600 and 5600 Systems which contain a MicroWell subsystem.

VITROS® System	Type of Affect
VITROS® 4600 or 5,1 FS Systems	• Software contains the anomaly • No MicroWell subsystem • Frequency of occurrence for MicroSlide and MicroTip subsystems is significantly reduced (i.e., **1 in 14 million**) • No further action is required.
VITROS® 250/350 Systems	• Software does not contain the anomaly • No MicroWell subsystem • Systems are <u>not</u> affected
VITROS® ECi/ECiQ Immunodiagnostic Systems	• Software does not contain the anomaly • Systems are <u>not</u> affected
VITROS® 3600/5600 Systems connected to enGen™ Laboratory Automation (or other automation track)	• Anomaly is associated with VITROS® Software. • Follow the instructions in the enclosed procedure

7. What assays utilize the MicroWell subsystem?

The following VITROS Immunodiagnostics assays utilize the MicroWell subsystem:

AFP	CA 15-3	Free T3	NTBNP	Total PSA II
Anti-HAV IgM	CA 19-9	Free T4	Progesterone	Total T3
Anti-HAV Total	CEA	FSH	Prolactin	Total T4
Anti-HBc	CK-MB	HBeAg	PSA	Toxoplasma IgG
Anti-HBc IgM	CMV	HBsAg	Rubella IgG	Toxoplasma IgM
Anti-HBe	Cortisol	HBsAg ES	Rubella IgM	TroponinI ES
Anti-HBs	Estradiol	Intact PTH	Syphillis TPA	TSH
Anti-HCV	Ferritin	LH	T3 Uptake	Vitamin B12
Anti-HIV 1+ 2	Folate	Myoglobin	Testosterone	Vitamin D Total
CA 125 II	Free PSA	N-Telopeptide	Total B-hCG II	

8. Will Quality Control testing identify if the issue occurred on my VITROS System?

Quality Control samples are expected to exhibit the same magnitude of bias as patient samples and would be detected if the results exceeded the QC limits. If an assay is calibrated at ambient temperature, quality control results may not detect the anomaly.