URGENT

Ortho Clinical Diagnostics

August 2018

URGENT PRODUCT CORRECTION NOTIFICATION

Potential for Unsuppressed Results using VITROS® 5600 Integrated Systems

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

This notification is to inform you that, under very specific circumstances, incorrect positioning of the sample metering proboscis on a VITROS 5600 Integrated System may cause an insufficient sample volume to be dispensed onto a MicroSlide without suppressing (preventing the reporting) of the potentially incorrect result.

If these specific circumstances occur, the proboscis may deposit fluid on the tip locator or top surface of the slide and transfer sample fluid into the incubator.

Name	Product Code (Unique Identifier)	Software Versions
VITROS® 5600 Integrated System	**6802413** (10758750002740)	**3.3.1 and Below**
VITROS® 5600 Integrated System Refurbished	**6802915** (10758750007110)	

Description of Issue

TE1-504 and TE1-594 condition codes are an indication that the sample metering proboscis may not be positioned correctly due to a mechanical issue or obstruction during metering when processing MicroSlide assays. After these codes occur, the proboscis will reset and prepare for the next aspiration/dispense cycle. These codes are specific for each sample and would be posted after all dispenses for that sample are complete.

The following are indications that this issue may have occurred:

Occurrence of multiple TE1-504 and/or TE1-594 condition codes **AND**

- Sample fluid is observed on the tip locator and/or
- Increased number of results with an out of range (OR) code or results outside of your supplementary range (SR) for a same sample and/or
- Multiple Metering dispense pressure codes occur on the same sample resulting in a Drop Error "DE" code.

NOTE: Isolated single occurrences of TE1-504 and TE1-594 condition codes without the additional indicators above may be observed which are not associated with a sample dispense, and therefore, these results are not affected.

Rate of Occurrence

Based on e-Connectivity® data, our analysis determined the rate of occurrence of potentially affected non-suppressed results in samples associated with these codes is 1 in 117,191 results.

Important to Note*: Not all occurrences of this issue lead to an incorrect result. Based on our complaint data where potentially affected assays were repeated, the rate of occurrence for an incorrect result due to this issue was 1 in 13,687,428 results. For systems experiencing frequent/multiple occurrences of these codes, the rate may be higher*.

Impact to Results

Mis-positioning of the proboscis may lead to an insufficient volume of sample being dispensed onto a MicroSlide and may lead to incorrect results. The risk to patients could range from minor to severe. For infants, seniors or critically ill patients, falsely low or high results (depending on the assay) for electrolytes, basic metabolic panel, bilirubin (for neonates), therapeutic drug monitoring assays, etc., could mislead physicians to delay or miss the detection of critical conditions.

A review of previous results may be impractical due to insufficient historical information. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

REQUIRED ACTIONS

- If you observe unexpected MicroSlide assay results for a sample associated with TE1-504 and/or TE1-594 condition codes, please do the following:
  - Inspect the tip locator to determine if sample fluid is present. Refer to example shown on page three.
  - If fluid is NOT observed, repeat all MicroSlide assays for the affected sample.
  - If sample fluid is observed on the tip locator or repeated results do not agree (i.e., incorrect results), contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre for further assistance.
- Complete the Confirmation of Receipt form no later than August 24, 2018.
- Post this notification by each VITROS 5600 System in your facility or with the user documentation.

Resolution

This issue will be resolved in the next software version expected to be released later in 2018. When this software is installed, the system will automatically suppress all results for any sample associated with TE1-504 and TE1-594 condition codes and will require the tests to be re-run.

For VITROS 5600 Systems that are e-connected: Ortho is monitoring e-connected systems for an increase in the frequency of TE1-504 or TE1-594 condition codes and, if indicated, will contact your authorized service representative to optimize your system. Upon request, we may be able evaluate your available historical data (up to 3 months) for unsuppressed results associated with these condition codes. To request a data review, contact your local Ortho representative or our Ortho Care Technical Solutions Centre for assistance. Turnaround time for completion of data review is dependent upon the number of requests we receive.

For VITROS 5600 Systems **not** e-connected: If you observe an increase in the frequency of TE1-504 or TE1-594 condition codes, contact your local Ortho representative or our Ortho Care Technical Solutions Centre for assistance.

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact your local Ortho representative or our Ortho Care Technical Solutions Centre at 1800-5646-766

Questions and Answers

1. Are other VITROS Systems affected?

This issue can only affect MicroSlide assays processed on VITROS 5600 Systems. No other assays (i.e., MicroTip or MicroWell) or VITROS Systems are affected.

2. How can I determine if sample fluid is present on the VITROS 5600 Tip Locator?

The photograph below shows an example of fluid on the tip locator: