

**URGENT FIELD SAFETY NOTICE****Potential for Unsuppressed Results using VITROS® 5600 Integrated Systems**

Dear Customer,

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics initiated this Urgent Field Safety Notice due to 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 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 a mis-positioning issue may exist:

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 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 the Ortho Care™ Technical Solutions Center for further assistance.
- Complete the Confirmation of Receipt form no later than **August xx, 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 will contact your authorized service representative to optimize your system, if appropriate. Upon request, we may be able to evaluate your available historical data (up to 3 months) for unsuppressed results associated with these condition codes. To request a data review, contact Ortho Care Technical Solutions Center 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 the Ortho Care Technical Solutions Center for assistance.

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact Ortho Care Technical Solutions Center at **insert appropriate number**.

Insert signatory if appropriate in your region

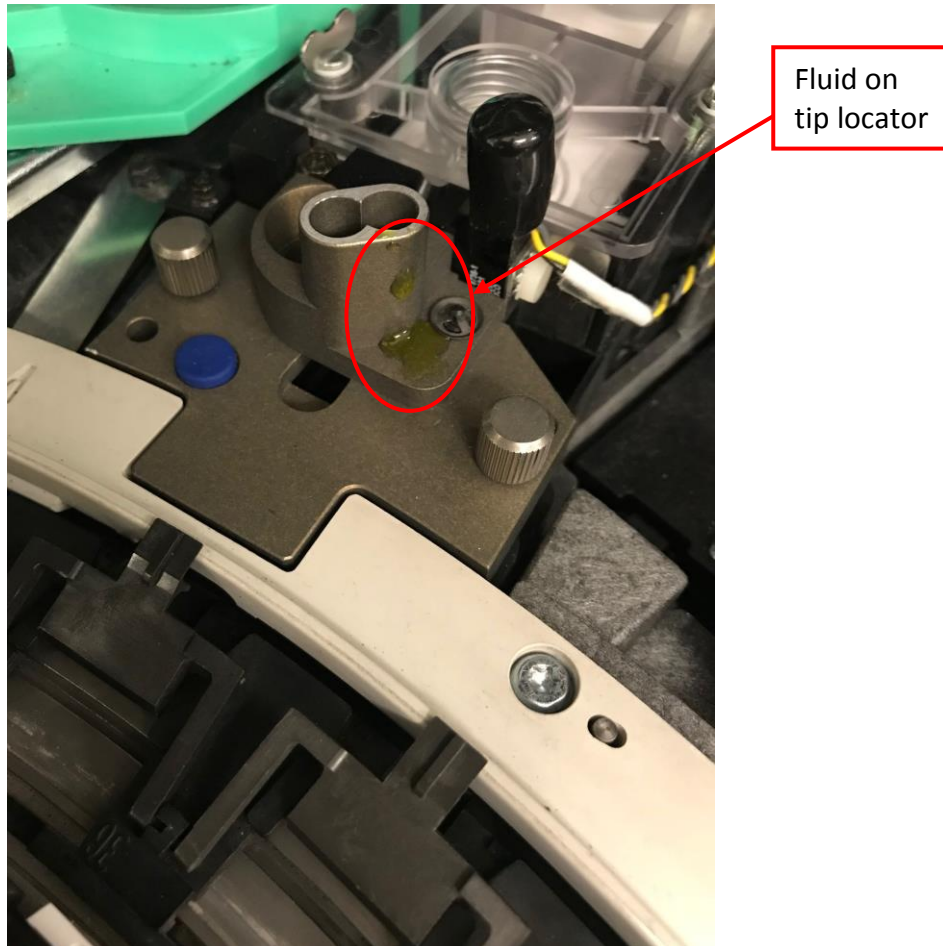
Questions and Answers

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:



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Please return completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:

xx-AUG-2018

Send to: **Insert name**

e-Mail

Address: **insert email address**

Fax: **Insert number**

Please Confirm

I received the Urgent Field Safety Notice with information that under specific circumstances, incorrect positioning of the sample metering proboscis on a VITROS 5600 System may cause an insufficient sample volume to be dispensed onto a MicroSlide without suppressing the potentially incorrect result.

I understand the information provided in the customer letter and will follow the instructions if I observe unexpected MicroSlide assay results for a sample associated with TE1-504 and/or TE1-594 condition codes.

Your signature provides confirmation that you have received and understand this notification.

Your Name: _____

Signature:
Required

Phone Number: _____ Date: _____

Your Comments: _____

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/

Contact Name: _____

Address: _____

City: _____

State/Prov: _____

Zip/Postal Code: _____

Phone: _____

Fax: _____

e-Mail: _____