



Month XX, 2020

URGENT FIELD SAFETY NOTICE
VITROS® Systems – Modifications to MicroWell
Qualitative Assay Parameters Not Retained

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides important information regarding a software anomaly affecting MicroWell qualitative assay parameters when used on certain VITROS Systems. This anomaly causes some modified qualitative assay parameters to be inadvertently reset to default in certain circumstances.



Affected Product Name	Product Code (Unique Identifier)	Software Versions
VITROS® 3600 Immunodiagnostic System	6802783 (10758750002979)	3.3.3 and below
VITROS® 3600 Immunodiagnostic System - Refurbished	6802914 (10758750007103)	
VITROS® 5600 Integrated System	6802413 (10758750002740)	
VITROS® 5600 Integrated System - Refurbished	6802915 (10758750007110)	
VITROS® XT 7600 Integrated System	6844461 (10758750031610)	3.5.1 and below

Note: The current software version number appears in the upper right corner of the system screen.

Background Information

The System Software allows customers to change the *Qualitative Result Text* and *Qualitative Ranges* for MicroWell Qualitative Assays in the **Options & Configuration – Configure Assays - Review/Edit Configuration** screen:

Screen example:

	<u>RANGES</u>	
1. Negative		<=0.89
2. Retest?	0.90	-0.99
3. Reactive	1.00	or greater
		
<i>Qualitative Result Text</i>	<i>Qualitative Ranges</i>	

If any of these fields (result text or ranges) are modified, results for the assay are given a M1 code. When an Assay Data Disk (ADD) is loaded selecting Retain Configuration, all edited fields associated with a M1 code **should** be retained. Selecting Restore Defaults will change all fields associated with a M1 code back to the default values.

Description of Issue

Current functionality automatically updates these values for Plasma when Serum is updated. Both Serum and Plasma user modifications in the Options & Configurations – Review/Edit Calibrations – Review Assay data screen **should** then be marked with M1 to ensure the modifications are retained when Retain Configuration is used during ADD load. Internal testing identified a software anomaly which occurs if the Qualitative Result Text and/or Qualitative Range settings are modified by the

operator for Serum, the corresponding values are updated for Plasma, however the M1 code is **not** assigned to Plasma. Therefore, after loading an ADD and selecting Retain Configuration, the modified Qualitative Result Text and Qualitative Ranges are retained for Serum, but the Plasma Qualitative Result Text and Qualitative Ranges **incorrectly** revert to the Default values validated by Ortho and recommended in the VITROS Immunodiagnostic Products Instructions for Use (IFU).

No other parameters are affected by this issue.

Only VITROS Qualitative Assays supporting Serum & Plasma may be impacted: HAV M, HAV T, aHBc, HBc M, aHCV, aHBs, aHIV 1+2, HIV c, HBsAg, HBsAg ES, Rub G, Rub M, Syph, Tox G, Tox M, aTCRU, CMV G, CMV M and CoV2T.

Note: aHBs is a quantitative assay that shares a system configuration similar to the qualitative assays and is therefore impacted by this issue.

If your laboratory has not modified Qualitative Result Text/Ranges for the assays listed above, your laboratory is NOT affected by this issue.

Impact to Results

If your laboratory modified the Qualitative Ranges, different ranges defining the Qualitative Result Text could exist for Serum and Plasma due to this software anomaly. Therefore, a plasma sample may not be evaluated with the ranges intended by your laboratory.

Example: If the “Borderline” category name was changed to “Retest” and the cutoff was modified from the default of 0.80 to 0.90 for serum, the change would automatically be applied to plasma. After the ADD was loaded, a sample with a value of 0.85 would report as “Negative” if run as a Serum sample, but “Borderline” (rather than the intended “Negative”) if run as a Plasma sample.

The default result interpretation recommended by the product IFU has been validated by Ortho and represents expected assay performance. However, if your laboratory has modified these values for your patient population, this anomaly could generate a result value that is not interpreted as intended for some Plasma samples.

If your laboratory has modified these values, we recommend you review your Plasma sample results and compare versus your intended thresholds.

Resolution

The anomaly will be resolved with software version 3.6, which is expected to be available in the third quarter of 2020.

In the meantime, manually adding the values in both the serum screen AND the plasma screen (even though the plasma screen appears to be updated already) will prevent the issue by correctly marking the edits to both body fluids with M1.

To manually enter these values for Plasma in Options & Configurations: navigate to Plasma, select the assay, select “Review/Edit Configuration”, edit Qualitative fields to match Serum. If it appears they currently match, retype at least one of the changes, then touch “Save”.

Once the Qualitative Range values have been updated, load an ADD using Retain Configuration. Verify that both Serum and Plasma values match the intended modifications. This indicates that the modifications were marked with a M1 code and will continue to be retained when that option is used during future ADD loads.

REQUIRED ACTIONS

- Review impacted assay list and determine if any modifications to the Qualitative Result Text/Ranges have previously been made to these assays by your laboratory in the Options & Configurations – Configure Assays - Review/Edit Configuration screen. If your laboratory has previously modified the Qualitative Values of one or more assays, do the following before further processing any of these assays:
 - Re-Load your current ADD, choosing Retain Configuration. If your system is e-connected, the current ADD can be reloaded even if it does not appear in the mailbox on the System Status screen.
 - Review the Options & Configuration – Review/Edit Configuration for each assay identified above. If the Plasma values do not match Serum, manually enter values into the Plasma screen so that Serum and Plasma match your intended modification. Repeat for each assay modified.
 - Re-Load your current ADD, choosing Retain Configuration. Verify your modifications were retained.
- A review of previously reported patient results is recommended if you identify an assay modification in which Serum and Plasma do not match. Review Plasma sample results for these assays versus your intended thresholds.

Note: if your VITROS System is connected via e-connectivity, the Ortho Care Technical Solutions Center can assist you with obtaining your patient results from the past 90 days.
- If you believe this software anomaly has affected sample results in your laboratory, please contact Ortho Care Technical Solutions Center.
- Complete the Confirmation of Receipt form no later than **Month ##, 2020**, even if your laboratory is unaffected by this issue.
- Please forward this notification if the product was distributed outside of your facility.

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 number**.

Insert signatory if appropriate in your region.