URGENT

Ortho Clinical Diagnostics

Month ##, 2021

URGENT FIELD SAFETY NOTICE

ORTHO VISION® Analyzer and ORTHO VISION® Max Analyzer
Potential for False Negative Results for Specific User Defined Protocol Configurations

Dear Customer,

The purpose of this notification is to inform you that the Wrong Liquid Level (WLL) check will not occur in specific configurations when using User Defined Protocols (UDP). You are receiving this letter because either your facility uses the UDP feature, or, your system is not e-connected and Ortho cannot evaluate the use of this feature on your analyzer(s).
If your facility does not use the UDP feature on your system, you are NOT affected by this issue.

Affected Product Name	Product Codes (Unique Identifier No)	Software Version
ORTHO VISION® Analyzer for ORTHO® BioVue Cassettes	6904579 (10758750012831)	APSW 5.13.0 and below
ORTHO VISION® Max Analyzer for ORTHO® BioVue Cassettes	6904578 (10758750012848)	

Background

ORTHO VISION Analyzer and ORTHO VISION Max Analyzer allow the user to configure User Defined Protocols (UDP). The UDP feature allows the user to expand the test menu beyond those tests currently available from Ortho-Clinical Diagnostics, Inc. (Ortho). UDP tests are created from a standard configuration, which includes volumes dispensed. However, dispense volumes can be configured by the user to other non-standard volumes.

The Wrong Liquid Level (WLL) check is a functionality of the CIMS (camera and imaging system) module capable of detecting if the fill volume of each BioVue Cassette is as expected.

If the fill volume detected in a single well is different from expected, the single well is marked with the 'WLL' code and the cassette/card is saved for the operator review.

Issue Description/Investigation

A complaint was received from a customer who set up a User Defined Protocol (UDP). When a dispense issue occurred, the result was reported as a negative reaction instead of flagging the result with WLL.

An internal investigation was conducted and it was concluded that if a user creates a User Defined Protocol and modifies the dispense volume of one or more reaction constituents such that the total expected fill volume is not 50, 90 or 100 uL, there is no Wrong Liquid Level check.

Impact to Results

A false negative reaction could be reported only if:

- The UDP is configured with a total cassette fill volume other than 50, 90 or 100 uL, **AND**
- A pipetting anomaly occurs that is not detected by another system mechanical verification, or not detected by Laboratory personnel during manual review of the cassette.

A false negative result in antibody screening/identification tests could miss a clinically significant antibody and the patient may be transfused with incompatible blood and a hemolytic transfusion reaction could occur. A false negative result of a crossmatch test could also lead to transfusion of incompatible blood and a hemolytic transfusion reaction.

The probability of an undetected false negative result is reduced as it can occur only if an undetected metering issue occurred. Therefore, repeat testing is not required. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

REQUIRED ACTION

- Review User Defined Protocols to determine if the total fill volume is something other than 50, 90 or 100 uL. Refer to the '*Reviewing UDP Volumes*' enclosure.
- If UDP tests are configured with non-standard volumes, disable the automatic results acceptance, and manually review cassettes for unexpected liquid levels.
- Consider reconfiguring UDP test to use standard volumes.
- Complete the enclosed Confirmation of Receipt form no later than MM/DD/YY
- Place this notification with your user documentation until such time as the User Defined Protocols (UDP) & User Defined Reagents (UDR) Guide is updated with this information.

Contact Information

We apologize for the inconvenience this may cause your laboratory. If you have further questions, please contact Ortho Care™ Technical Solutions Center at *insert appropriate number* / *insert signatory if required*

Enclosures:
Instructions for Reviewing UDP Volumes (Ref. CL2021-080_UDP_BV)
Confirmation of Receipt Form

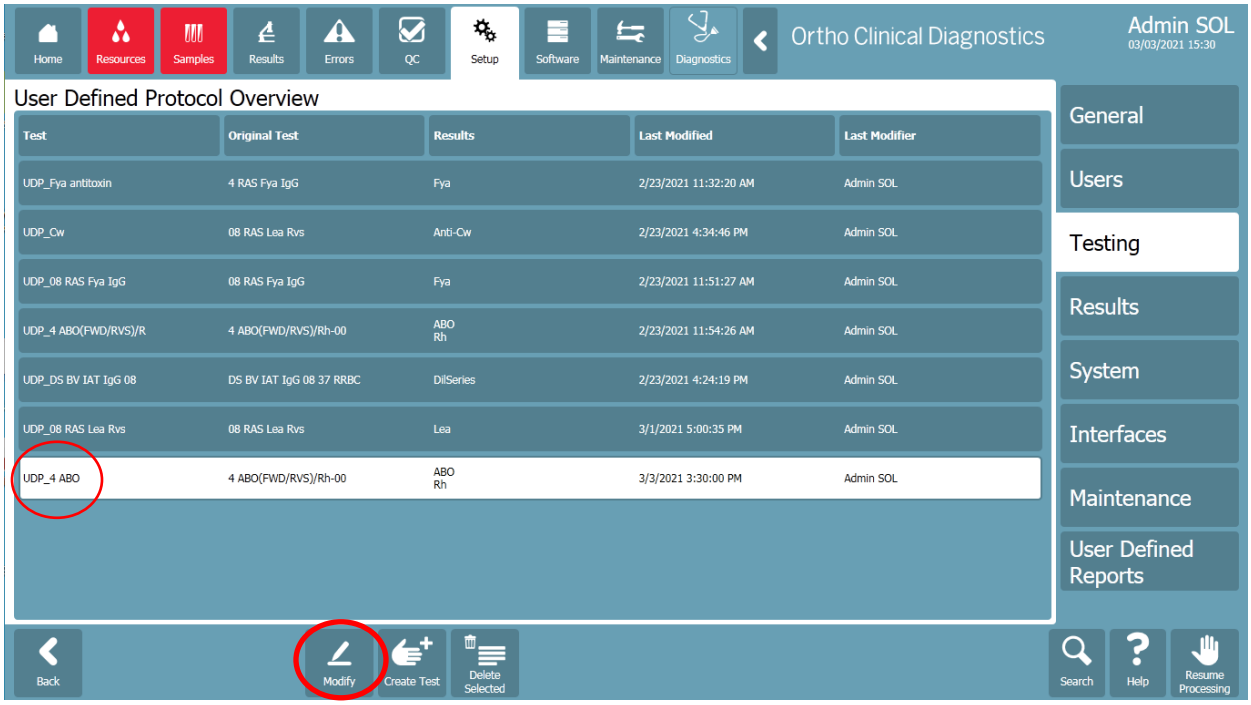
Instructions to Verify User Defined Protocol (UDP) Configuration and Disable Automatic Result Acceptance

Verify UDP Configuration

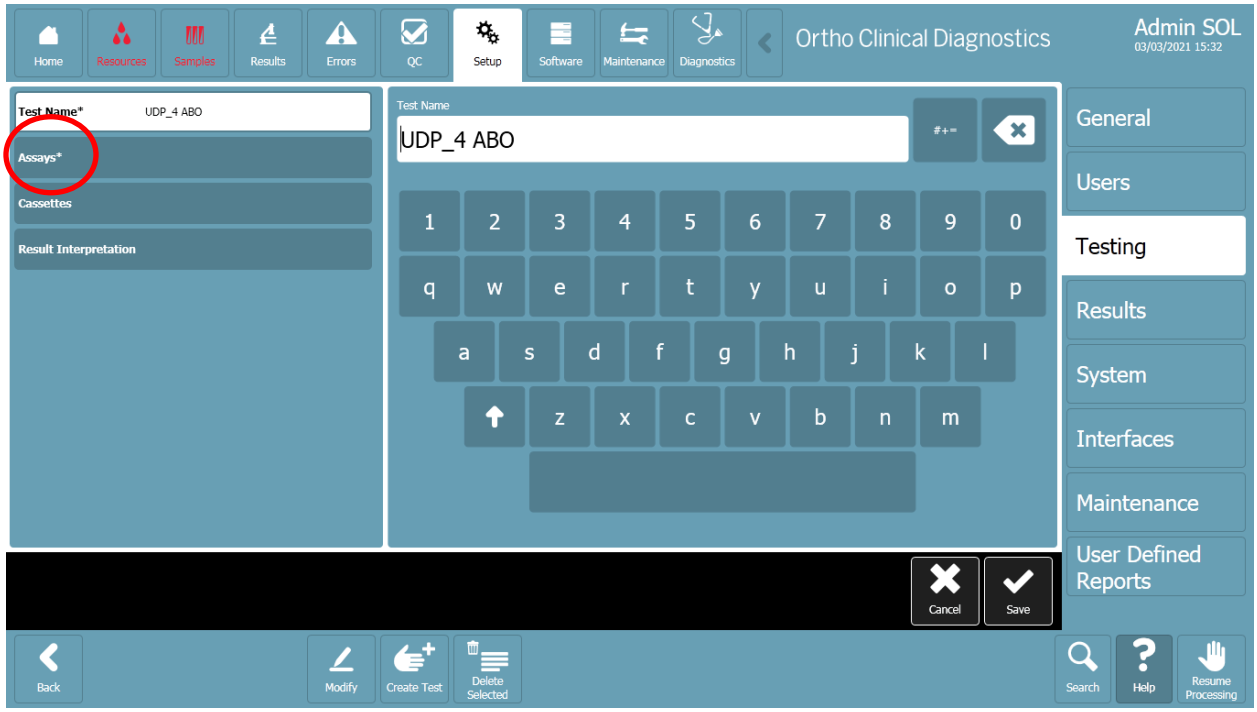
Each UDP test must be verified separately.
To verify UDP configuration, first delete all Profiles related to the UDP.
To delete the Profile, all results related to this Profile need to be archived in Results Tab.

In Setup > Testing

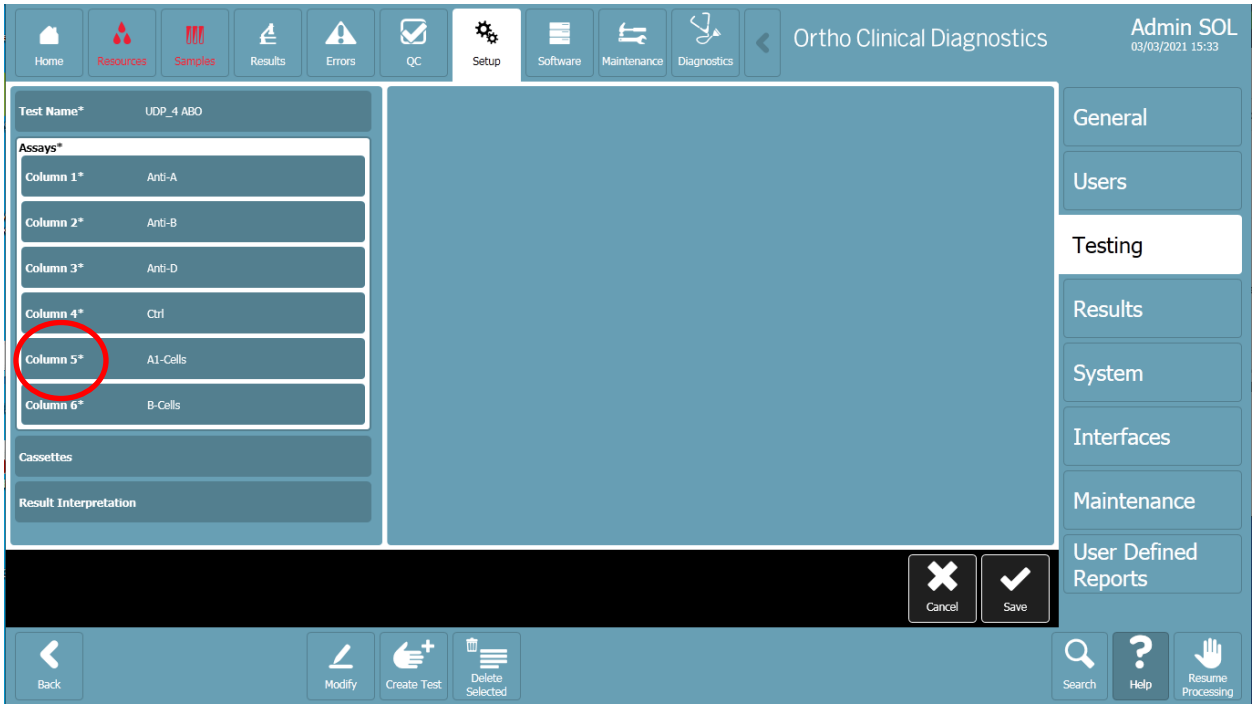
- Select UDP
- Select Modify



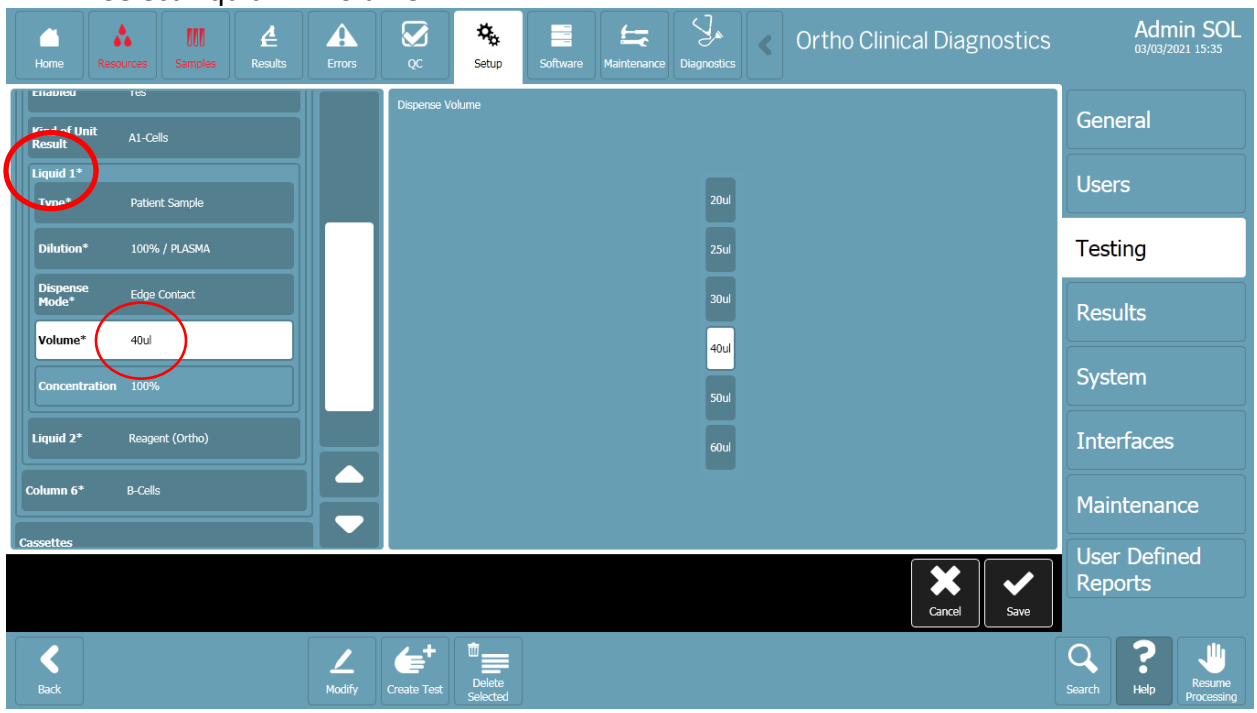
- Select Assays



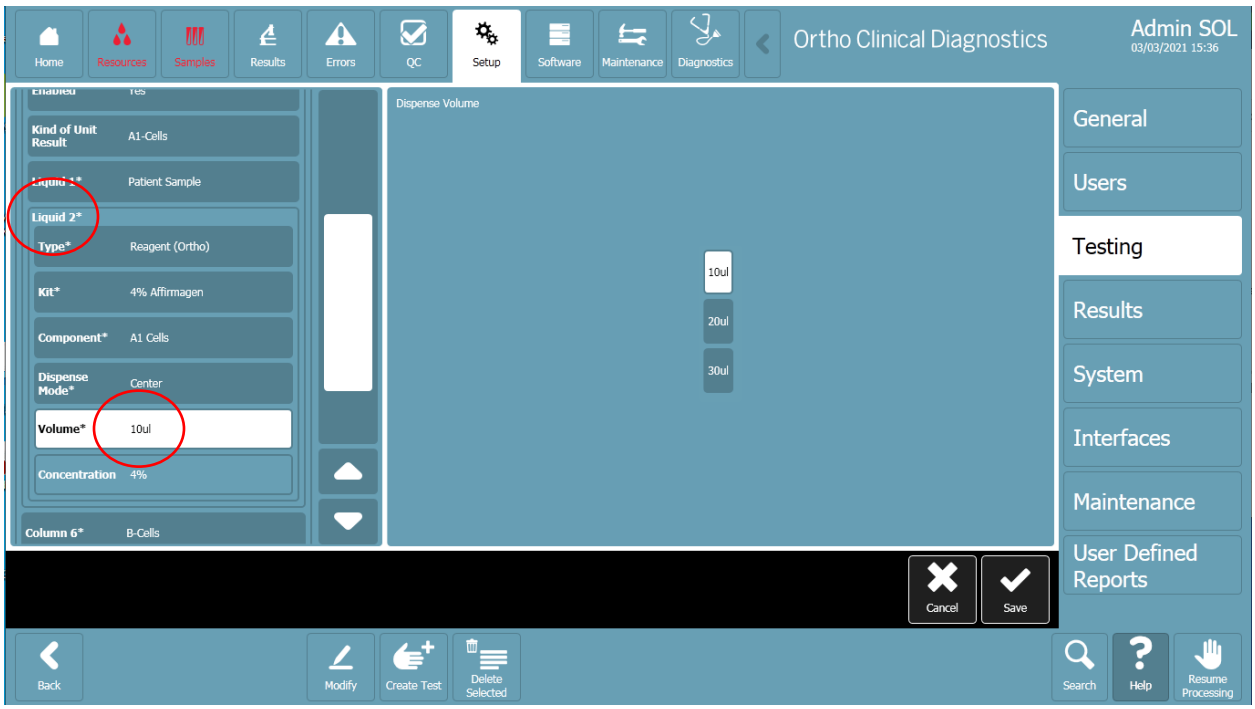
- Select all Columns, one by one



- Select Liquid 1 > Volume



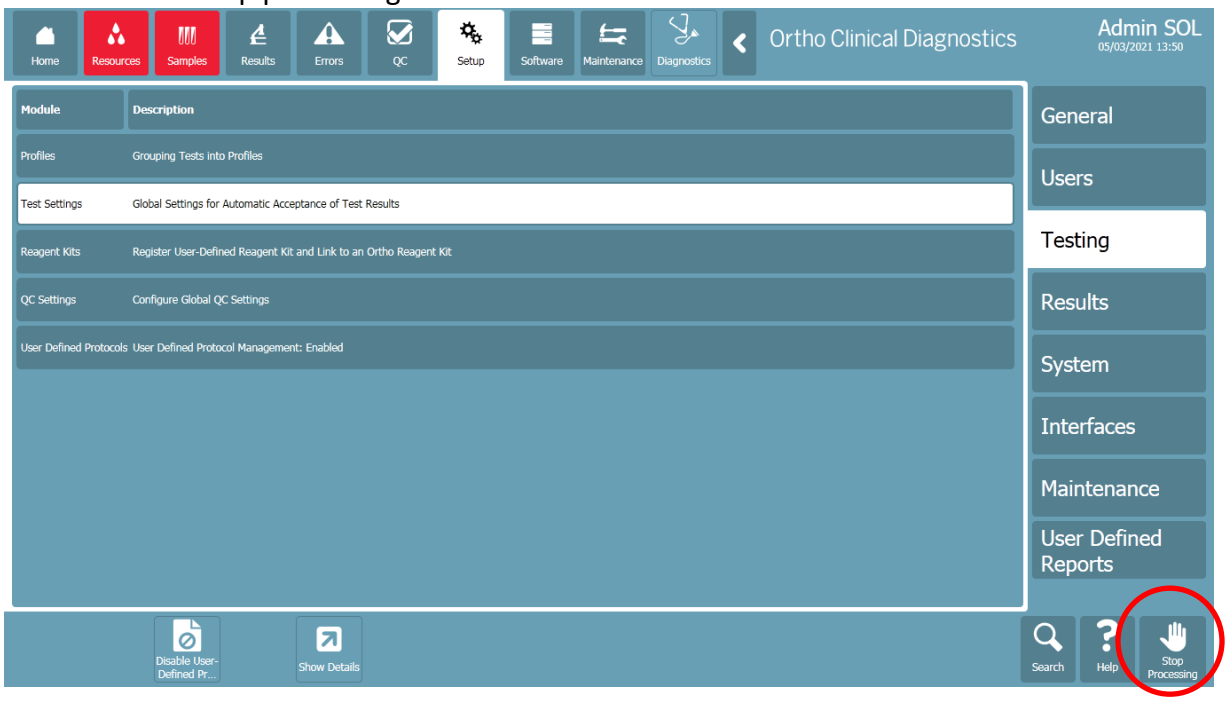
- Select Liquid 2 > Volume



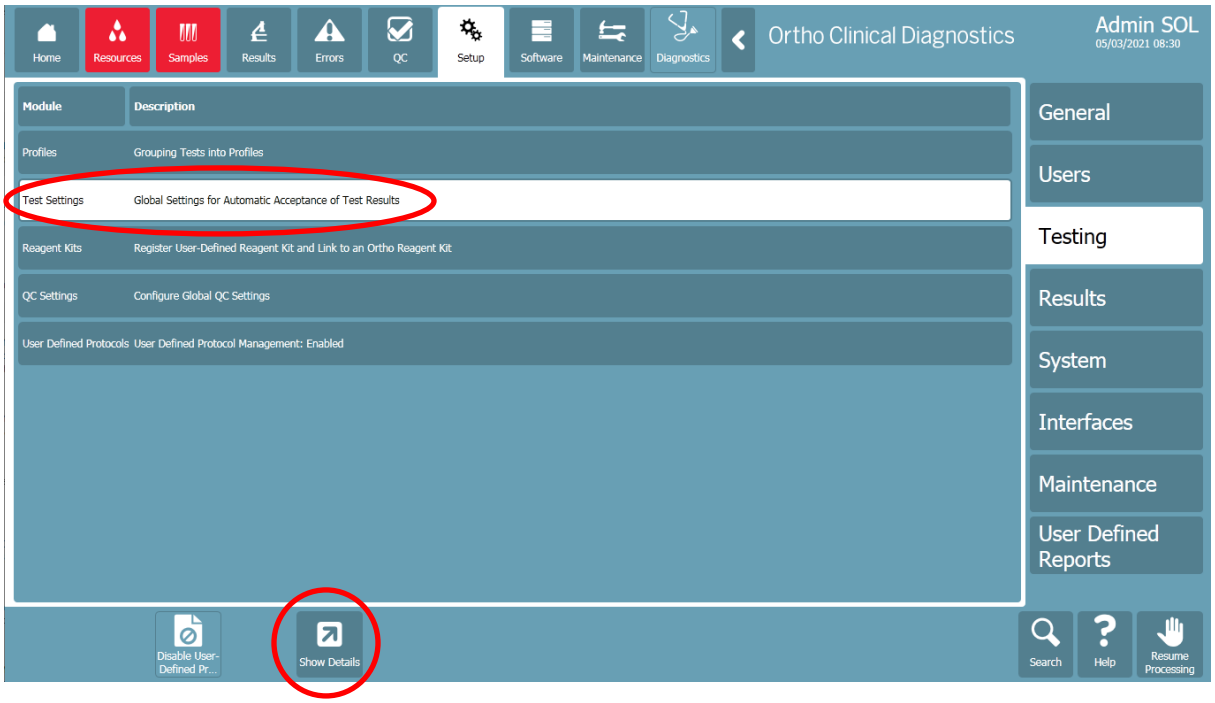
- Select Liquid 3 (when applicable) > Volume
- Check if total fill volume (sum of all liquids volume) is different than 50, 90 or 100 uL.

Disabling the Automatic Result Acceptance of UDP

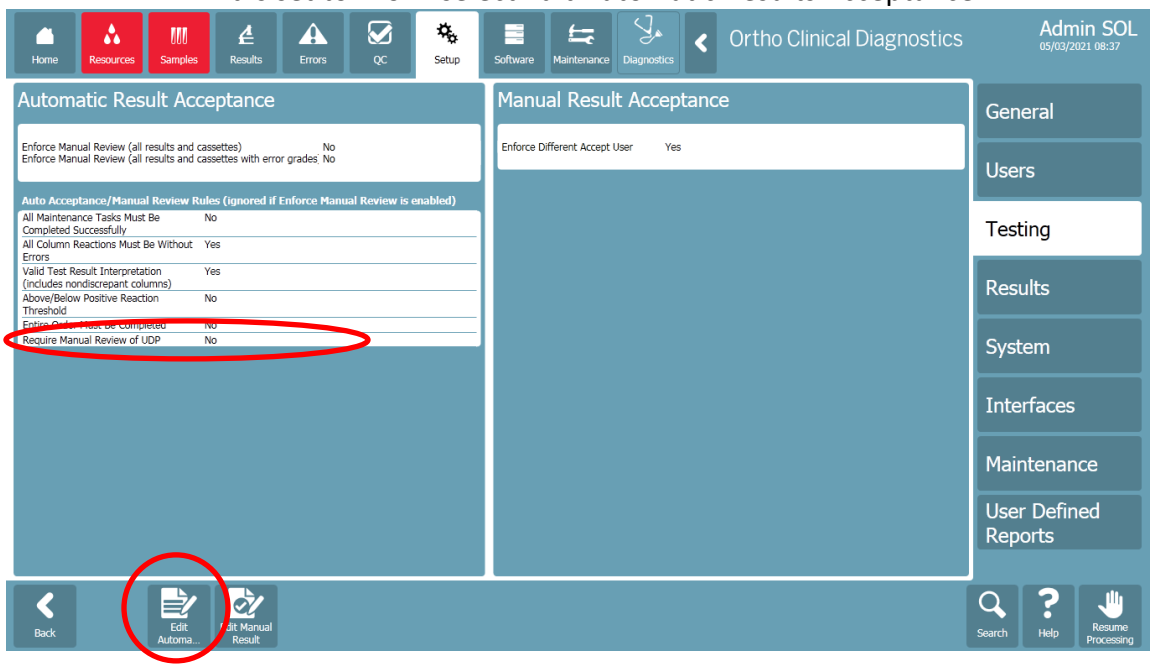
- Go to Setup> Testing
- Hit the Stop processing button



- Select Test Settings > Show Details



- If you are working in automatic acceptance result mode:
  Verify if Required Manual Review of UDP is set to ‘Yes’.
  If it is set to ‘No’ > select Edit Automatic Results Acceptance



- Change Requires Manual Review of UDP to ‘Yes’
- Save modification

Confirmation of Receipt – Response Required

Communication ID: CL2021-080 Date of Issue: 2021-MM-DD

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

Send to: Name e-Mail Address: email address Fax: Fax Number

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: _____

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2021-080_BV_EU) regarding no Wrong Liquid Level (WLL) check on User Defined Protocol (UDP) tests when the total volume is non-standard.

Please choose from the following:

- ☐ My laboratory does not use the UDP functionality.
- ☐ My laboratory does use UDP test(s), however the total volume dispensed matches the standard volumes listed in the notification.
- ☐ My laboratory does use UDP test(s) with a total volume other than the standard volumes listed in the notification. I understand automatic results interpretation should be disabled and cassettes should be manually reviewed for unexpected liquid levels.

Signature:
Required
Your signature confirms that you have received and understand this communication

Print Name: _____

Phone Number: _____ Date: _____

Your Comments: _____