

Thermo Fisher Scientific Niche Diagnostics Center of Excellence Clinical Diagnostics 46500 Kato Road, Fremont, CA 94538 510-979-5000 510-979-5002 fax www.thermoscientific.com

Date:January 17, 2020To:Laboratory Director, Laboratory Manager and Laboratory PersonnelSubject:LabLink xL Software Release Notes – Version 2.1.4.6.5

Dear LabLink xL Software User,

As part of Thermo Fisher Scientific's mission to continuously improve customer satisfaction and the quality control management process, we will release the following updates to Thermo Scientific[™] LabLink xL[™] software on January 31, 2020. A restart of your computer or Auto-Connectivity software may be required after the update to restore any automated data transfer processes to LabLink xL software. Below are the release notes for version 2.1.4.6.5.

General Improvements

1. The "RE-VALIDATE DATA" feature now removes existing electronic signatures associated with the original data point(s).

Fixes

- 2. Modified the file reader to check the completeness of text files containing the exported QC results.
- 3. The Comment icon under the Daily Data screen no longer displays a "-" when data points are imported using the Cloud Communicator.
- 4. The Validation Error message on the Global Review page is now aligned and displayed properly.
- 5. Removed the "Out of Package Insert Range" exclusion display on the Levey-Jennings Chart and the Daily Data screen.
- 6. The check boxes on the Quality Control Setup screen will now resize according to the window aspect ratio.
- 7. The "CANCEL" button on the Quality Control Setup screen is now aligned correctly when the window is resized.
- 8. Corrected an issue where the selected date would revert to the current date on the Submit screen (applicable only to users viewing the software in the Chinese language).



General Improvements

1. The "RE-VALIDATE DATA" feature now removes existing electronic signatures associated with the original data point(s).

This feature is available for both Intermediate and Elite Users. The feature may be accessed from the Quality Control Setup screen \rightarrow Westgard Setup screen \rightarrow Data Re-Validation

		Qua	lity Co	ontrol	Setup -	Thermo Fish	er Sclentlfi	c (555	555) - ***T	EST LAB***			
Westgord Setup						RINBAK Setup							
Test		Rules Selection	Rules Selection				Target Ra	Target Range					
Lab:	Thermo Fisher Scientific	Rute	0	Iff	Warn	Reject	Lot Number	Method	Reag	ent Target Mean	Target SD	-2 50	+2 50
Instr:	BECKMAN UniCel DxI 600/800 (test - np)	1-25			0	0	CXL2001L	BNP2	ALERE (Blosit Diagnostic)	te [No Results.	No Results.
Product:	MAS CardioImmune XL	1-2.5s			0	0	CKL20011	BNP2	ALERE (Blosit Diagnostic)	te		No Results.	No Results.
Test:	BNP	1-3s		9	0	0	CXL20012	BNP2	ALERE (Blosit Diagnostic)	te 📃		No Results.	No Results.
							CKL20013	BNP2	ALERE (Biosil Diagnostic)	te		No Results.	No Results.
Mean/SL) Criteria						-						
Mean/SD	Criteria:	Across Contr	ol, With	nin Run			Total Allo	owable	Error				
User De	fined Range 🔹 🔻	Ru	Rute Off			Varn Reject	Type of Quality Goal:						
Min. # of	Data Pointsi	2-2s (Across Co	2-2s (Across Control)			0 0	Custom						
							Quality G	al Unit o	f Measure:				
-							96						Ŧ
Data Re-	Validation	Within Contro	Acro	cc Run									
From Date:		Rute	Off	Warn	Reject	Points	Lot Nun	nber	Method	Reagent	Q	uatity Goat	
1/7/2020		2-25		0	0		CXL20011		BNP2	ALERE (Biosite Diagnostic)			0.00
	RE-VALIDATE DATA >								0100	ALE DE 10 10 10 10 10			
		2 of 3-2s	۲	0	0		CKL20012		BNP2	ALERE (Biosite Diagnostic)			0.00

Previously, LabLink xL software would not allow users to re-validate data points that are associated with an electronic signature. Now, users will be able to re-validate data points even with an attached electronic signature. LabLink xL software will remove the previous electronic signature and its associated comments for all re-validated data points.

Users will then need to re-enter their login profile for audit trails.

Please note that the data re-validation will affect only data points for the selected profile of: Lab, Instrument, Product, and Test.

A new pop-up message will display as follows when "RE-VALIDATE DATA" is selected for data points that have an associated electronic signature:

1/10/2020 shall be REMOVE	D.
Please confirm by providing	your login credentials.
Email Address	
Password	
	CONFIRM

Fixes

2. Modified the file reader to check the completeness of text files containing the exported QC results.

Previously, a delay that occurred: 1) during the export of QC results to a text file and 2) when the Auto-Connectivity software pulls the text file to transfer into LabLink xL software, would result in data truncation in the last row of the QC results file.

The file reader has been enhanced to confirm the completeness of each row in the text file.

3. The Comment icon under the Daily Data screen no longer displays a "-" when data points are imported using the Cloud Communicator.

In the Daily Data screen, LabLink xL software previously displayed a "-" as a Comment underneath the Comment icon. This would occur only when the data point was imported using Cloud Communicator.

This issue has been rectified so that the "-" symbol no longer displays with the Comment icon.

4. The Validation Error message on the Global Review page is now aligned and displayed properly.

Previously, the Validation Error message was not aligned and displayed properly on the Global Review page. This has been rectified.

5. Removed the "Out of Package Insert Range" exclusion display on the Levey-Jennings Chart and the Daily Data screen.

The "Out of Package Insert Range" exclusion message had displayed on the Levey-Jennings Chart and the Daily Data screen previously. This has been removed to avoid any confusion as to whether the Lab-Target-Range or the GOR range generated the exclusion flag.

6. The check boxes on the Quality Control Setup screen will now resize according to the window aspect ratio when using Google Chrome or Firefox browsers.

There was previously a re-sizing issue pertaining to the checkboxes on the Quality Control Setup screen when using Google Chrome or Firefox browsers. The check boxes will now resize according to the window aspect ratio when using Google Chrome or Firefox browsers.

7. The "CANCEL" button on the Quality Control Setup screen is now aligned correctly when the window is resized.

Previously on the Instrument Setup section under the Quality Control Setup screen, the "CANCEL" button would shift and overlap other fields on the screen when the window aspect ratio was adjusted. This issue has been rectified.

8. Corrected an issue where the selected date would revert to the current date on the Submit screen (applicable only to users viewing the software in the Chinese language).

On the Submit screen, users viewing the software in the Chinese language were previously experiencing an issue where a selected date (any date prior to the current) would revert to the current date. This issue was related to the date format and has been rectified. If you have any questions or concerns, or would like help using these features, please do not hesitate to contact your Thermo Fisher Scientific representative or call our USA Technical Service Team at 800-232-3342 (select Option 2 followed by Option 1). You can also email us at <u>lablink.qap@thermofisher.com</u>.

Sincerely,

John Mohte

Arjun Mehta Product Manager Clinical Diagnostics Division Thermo Fisher Scientific

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