

Product Bulletin

Date: July 14, 2021
To: Laboratory Director, Laboratory Manager and Laboratory Personnel
Subject: **LabLink xL Software Release Notes – Version 2.1.5.5**

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 July 31st, 2021. During the update window, LabLink xL servers will be offline. Auto-Connectivity software will continue to collect data throughout the planned maintenance and automatically transmit it to LabLink xL after the servers come back online. While usually not necessary, 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.

Upon the successful rollout of the new release, a notification about the changes will display when you log in for the first time. Below are the release notes for version 2.1.5.5.

GENERAL IMPROVEMENTS

1. New Missing QC feature for alerting Users when QC data is not received within the Laboratory's configured timeframe.
2. New Event Type Tracking feature allows Users to associate specific event types with a given date/time.

FIXES

3. Fixed an issue where data was not displaying on the Levey-Jennings graph when the apostrophe punctuation mark was inputted in the comments section.

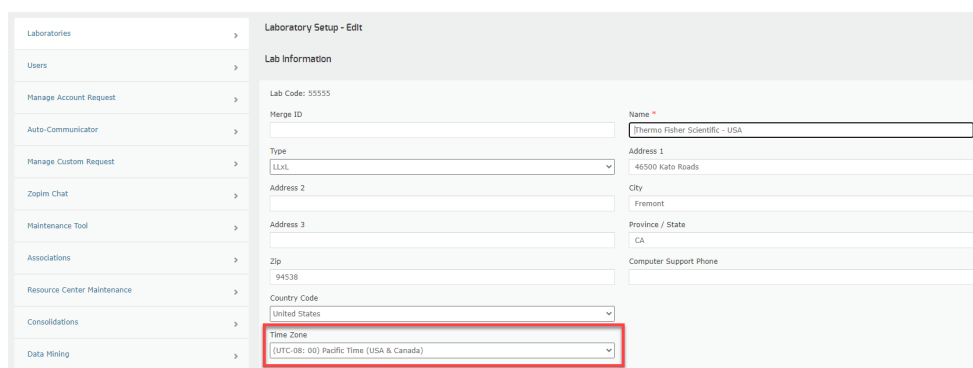
General Improvements

1. New Missing QC feature for alerting Users when QC data is not received within the Laboratory's configured timeframe

LabLink xL software now supports Missing QC alerts when QC data has not been received within the laboratory's specific time period. This feature is configurable on the laboratory level and will therefore apply to all Users associated with the given laboratory.

This feature is configurable by User Elite and User Intermediate permission levels. It is also specific to laboratory accounts that have the Daily Module enabled.

To access this feature, navigate to **Settings > Laboratories > Edit**. Ensure the laboratory time zone is configured correctly. This time zone is required as it will be used to calculate the hour(s) difference between each data point to confirm whether any QC data points are missing.



The screenshot shows the 'Laboratory Setup - Edit' interface. On the left is a sidebar with navigation links: Laboratories, Users, Manage Account Request, Auto-Communicator, Manage Custom Request, Zoplin Chat, Maintenance Tool, Associations, Resource Center Maintenance, Consolidations, and Data Mining. The main area is titled 'Lab Information' and contains various input fields. The 'Time Zone' dropdown menu is highlighted with a red rectangle, displaying the selected option: '(UTC-08: 00) Pacific Time (USA & Canada)'.

Setting up the Laboratory Time Zone

Navigate to **Settings > Missing QC Reminders Setup**. Select the appropriate Department, Instrument, Lot, and Test to apply the Missing QC Reminders.

Missing QC Reminders Setup - Thermo Fisher Scientific - USA (55555)

This page is used to setup how frequently QC tests are expected to be run. If QC data is not received within the timeframe configured here, it will be flagged on the Daily Data Table

Department:

Chemistry
▼

Instrument:

< ALL >
▼

Lot:

< ALL >
▼




Test:

< ALL >
▼

Time zone not configured. You can configure it in the Lab settings





Setting up the Missing QC Reminder Configuration

Once the appropriate Instrument(s), Lot(s), and Test(s) are selected, scroll down the page and input the number of hours under the respective fields for “Warning Time Out” and “Action Time Out”.

Instrument 	Lot	Test	Warning Time Out (in hours)	Action Time Out (in hours)
ABBOTT AEROSET, Test Release	AA22021A	Ammonia	1 	3 
ABBOTT AEROSET, Test Release	AA22022A	Ammonia	<input type="text"/>	<input type="text"/>
ABBOTT ALINITY C, Chemistry	CXL21121	Creatine Kinase-MB (CK-MB)	<input type="text"/>	<input type="text"/>

In the example image above, the application will display a yellow warning on the Daily Data screen if more than 1 hour has passed and no QC data has been submitted for that profile. The application will display a red action time out on the Daily Data screen if more than 3 hours have passed and no QC data has been submitted for that profile.

Selecting the down arrow icon (refer to image below) will auto-populate the same hour value inputted in the first row.

Warning Time Out (in hours)	Action Time Out (in hours)
1 	3 
1 	3 
1	3

A pop-up message will display to confirm the request.

Are you sure you want to set this value to all the fields in this column?

YES
NO

Please note that the hour value will only populate on the same page; therefore, it will not carryover to the next page. To auto-populate the same hour on the next page, select the next page at the bottom of the screen and repeat.

Once the “Warning Time Out” and “Action Time Out” hours are inputted, ensure the **SAVE** button is selected at the bottom right of the page.

Whenever a new Instrument, Product, and QC Lot is added, the Missing QC Reminder will not be set automatically. Therefore, please ensure to update the Missing QC Reminder configuration for the new profile. To use an existing Missing QC Reminder configuration for a new Instrument and QC Lot, use the **Copy** feature under the “MY INSTRUMENTS” tab.

Existing Instrument:


Navigate to **MY INSTRUMENTS > Options > Copy** (see image below)

DASHBOARD
MY INSTRUMENTS
SUBMIT
REVIEW
REPORTS
DATA
RESOURCE CENTER

Lab Home - Thermo Fisher Scientific (55555) - ***TEST LAB***

Department:
General

[ADD NEW INSTRUMENT >](#)

Order	Instrument Model	Serial Number	Options
+	ADVANCED BILIRUBINOMETER	123abc	
+	AB150 pH Meter	123po	<div style="border: 1px solid red; padding: 2px; display: inline-block;"> Copy Copy </div>

Existing QC Lot:

Navigate to **MY INSTRUMENTS > Options > Config > Copy**

The screenshot shows the 'Instrument Configuration' interface. On the left, there are fields for 'Instrument Model' (ADVANCED), 'Serial Number' (123abc), and 'Color In Reports'. On the right, there is a table with columns for 'Product', 'Lot', 'Data Entry Format', and 'Options'. The 'Options' column has a dropdown menu with 'Copy' highlighted. Other options include 'Edit', 'Archive', and 'Delete'. There are also 'ADD QC', 'PRINT', 'DELETE', and 'EDIT' buttons.

Reviewing Missing QC on the Daily Data screen

Once the configurations have been saved, the QC Scheduling Reminder will be configured for the given profile(s). Any data points not received within the configured hours will display as a pop-up reminder each time the User navigates to **Review > Daily Data**.

QC Not Received ⓘ							
The warnings below indicate that QC data has not been received within the timeframe specified by your lab settings.							
Date	Time	Instrument	Lot	L	Test	Units	Result
6/30/2021	10:25 AM	ABBOTT ALINITY I, I	LIA24093A	3	Alpha-Fetoprotein (AFP)	ng/mL	Not Received
		ABBOTT ALINITY I,	CXL20121	1	Troponin I, High Sensitivity (hsTNI)	pg/mL	Not Received

Time Zone: (UTC-04:30) Caracas

Last Data Point Received: 2021-06-30 10:25:00

Current time: 2021-06-30 13:00:02

Configured (warning/action): 1 hour(s) / 3 hour(s)

Difference: 2 hour(s)

A tooltip will be displayed when Users hover over the actual time stamp under the "Time" column (refer to image above):

- **Time zone:** The lab configured time zone
- **Last Data Point Received:** The time when the last QC data point was received
- **Current time:** The local system time
- **Configured:** The hours configured for Warning and Action under **Settings > Missing QC Reminders Setup**

- **Difference:** The total difference in hours between the Last Data Point Received and the Current time

Please note that if no Date or Time displays for a given profile, this indicates no data point has been received since the Missing QC feature was enabled for the given profile.

QC Not Received ⓘ							
The warnings below indicate that QC data has not been received within the timeframe specified by your lab settings.							
Date	Time	Instrument	Lot	L	Test	Units	Result
		ABBOTT ALINITY I, I	CXL20121	1	Troponin I, High Sensitivity (hsTNI)	pg/mL	Not Received
		ABBOTT ALINITY I, I	CXL20122	2	Troponin I, High Sensitivity (hsTNI)	pg/mL	Not Received
		ABBOTT ALINITY I, I	CXL20123	3	Troponin I, High Sensitivity (hsTNI)	pg/mL	Not Received

Clicking on the blue tooltip displayed next to the “QC Not Received” text will display an explanation of the warnings on the pop-up window.

QC Not Received ⓘ							
The warnings below indicate that QC data has not been received within the timeframe specified by your account settings. If you believe QC data was submitted and that a warning is incorrectly displayed below, please ensure that the QC data point was transmitted to LabLink xL. If you use an automated data transfer solution or file upload to transmit data, please check the Data page and ensure the transmitted files have finished processing							
Date	Time	Instrument	Lot	L	Test	Units	Result
		ABBOTT ARCHITECT i1000SR, 111	9GQ203	2	Hemoglobin A1c	%	Not Received
		BECKMAN SYNCHRON LXi, 123 - MQC	8KQ102	1	Albumin	g/L	Not Received

The same information from the “QC Not Received” pop-up window will also be displayed when the “Missing QC” checkbox is selected on the Daily Data screen.

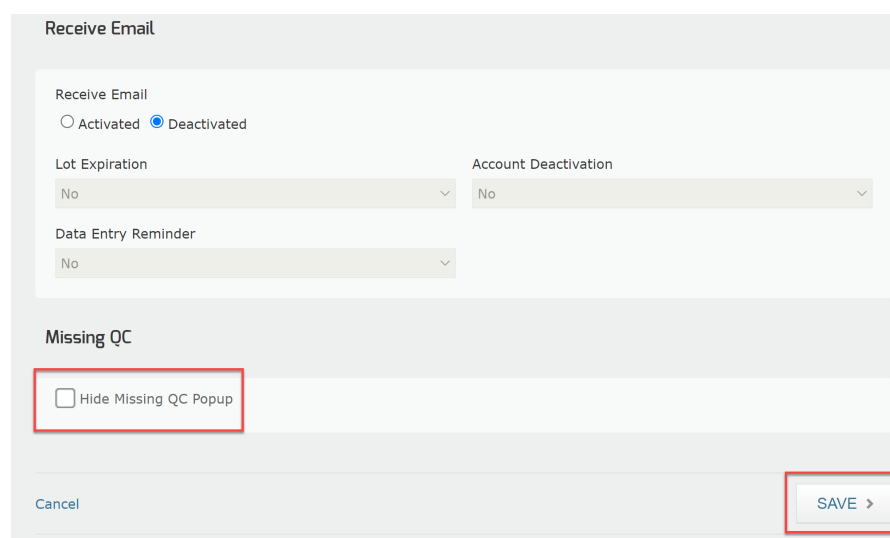
Display Only:																			
<input type="checkbox"/> Warnings		<input type="checkbox"/> Exclusions		<input checked="" type="checkbox"/> Missing QC ⓘ															
Date	Time	Instrument	Lot	L	Test	Units	Result	User	ZScore	Flags	Excluded	Target Mean	Target Range	RUBAK Target	RUBAK Range	Period Mean	Period Range	Reviewed	Approved
5/18/2021	5:56 PM	ABBOTT ARCHITECT i1000SR, 111	9GQ103	1	Hemoglobin A1c	%	Not Received	andrea.jettieri	-			-	-	-	-	30.0	30.0 - 30.0		
5/18/2021	5:56 PM	ABBOTT ARCHITECT i1000SR, 111	9GQ203	2	Hemoglobin A1c	%	Not Received	andrea.jettieri	-			-	-	-	-	50.0	50.0 - 50.0		

Please also note that the red exclamation icon next to the Missing QC checkbox will display if there are any data points that have not been received per the Missing QC Reminders Setup configuration.

When a data point is received for the Missing QC profile, the Missing QC warning alert will automatically be removed from both the “QC Not Received” pop-up window and the Missing QC data table.

Disabling the QC Not Received Pop-up

To disable the pop-up window that displays “QC Not Received” for any given User on the **Review > Daily Data** screen, navigate to **Settings > Users** and select **Options > Edit** for the specific User profile. Scroll down to the bottom on the “User Setup” page, select the checkbox next to “Hide Missing QC Popup”, and click **SAVE**.



The screenshot shows a 'User Setup' form. The 'Receive Email' section has 'Deactivated' selected. The 'Lot Expiration' and 'Account Deactivation' dropdowns are set to 'No'. The 'Data Entry Reminder' dropdown is also set to 'No'. In the 'Missing QC' section, the 'Hide Missing QC Popup' checkbox is checked and highlighted with a red box. At the bottom right, the 'SAVE >' button is also highlighted with a red box. A 'Cancel' button is visible at the bottom left.

2. Event Type Tracking feature allows Users to associate specific event types with a given date/time

LabLink xL software now supports Event Type tracking, which can be easily viewed on the Levey-Jennings screen. This feature is configurable on the laboratory level and will therefore apply to all Users associated with the given laboratory.

This feature is configurable by the following user permission levels:

- User Elite
- User Intermediate
- User Basic w/Review & Approve
- User Basic w/Review + Config

The feature is also specific to laboratory accounts that have the Daily Module enabled.

Setting up a Custom Event Type

To access this feature, navigate to **Settings > Event Types**. Click on “ADD NEW”. Input the information for each respective field.

Event Type - Add New - Thermo Fisher Scientific - USA (55555)

Code

Name

Color in Chart

Background Color

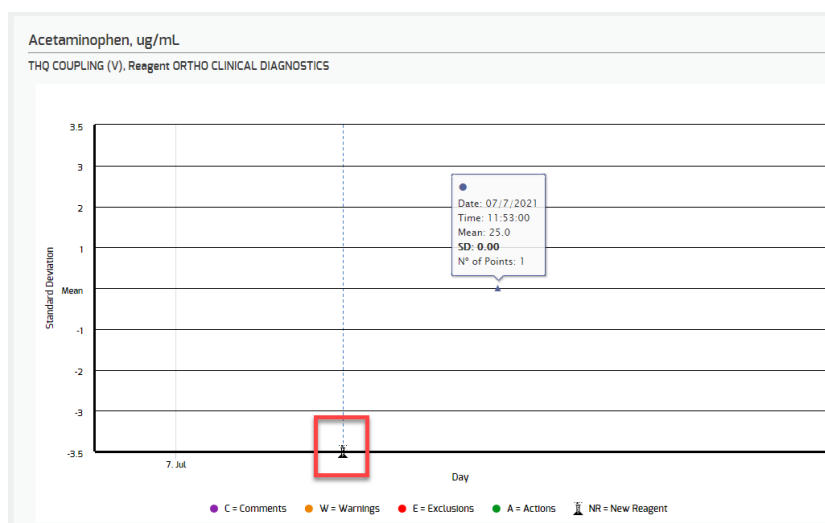
Icon

< Empty >

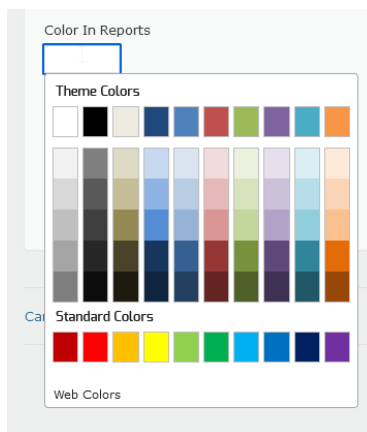
Cancel

SAVE >

- **Code:** unique identifier Code containing 2 letters (A to Z). For example, a “New Reagent” event type may be identified using the code “NR”.
- **Name:** Name of the event. For example, the event type could be called “New Reagent” and this would populate under the LJ chart in the legend.



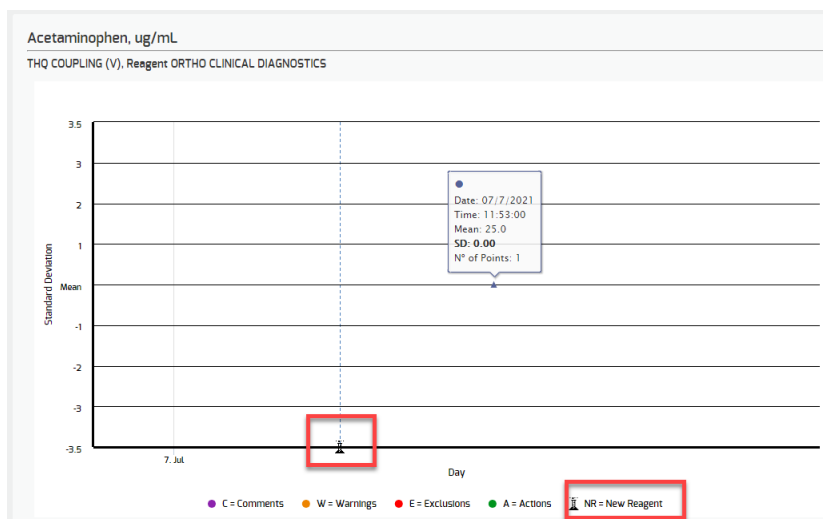
- **Color in Reports:** This displays the line color in the Levey-Jennings chart. Selecting the empty control will open up a color palette to choose.



- **Background Color:** This displays the background color of each event type row on the data table

Date	Instrument	Lot	L	Test	Units	Result	User	Flags	Excluded	Target Mean	Target Range	RitBAK Target	RitBAK Range	Period Mean	Period Range	Reviewed	Approved	Monthly Review
Acetaminophen, ug/mL																		
7/7/2021 11:53 AM	ORTHO VITROS 5600, test	CHU21111A	1	Acetaminophen	ug/mL	25.0	John Smith		<input type="checkbox"/>	-	-	-	-	25.0	25.0 - 25.0	<input type="checkbox"/>		
Event List																		
7/7/2021 6:11 AM	ORTHO VITROS 5600, test	CHU21111A	1	Acetaminophen	Event Type: New Reagent	John Smith	Reagent Changed											

- **Icon:** This is the icon to associate with the specific event type in the Levey-Jennings chart. This is available from a pre-defined list.



Select **SAVE** and the new event type will be added.

Code	Event Type	Background Color	Color in Chart	Icon	Options
NR	New Reagent				

Adding New Events from the “Event/Action Log”

Events may be added from two different locations:

- Event/Action Log
- Levey-Jennings Tab

For adding new events from the Event/Action Log, navigate to **Settings > Event/Action Log**. A list of existing events will display on the page.

Click on “ADD NEW” to create a new event for a specified Date and Time.

Select/input into the following fields for a new event:

- Instrument
 - When “ALL” is selected, this indicates that the event is not tied to a specific instrument or data point. Rather, it

is considered a global event (e.g. Preventative Maintenance, Power Outage, Raw Material Change, etc.).

- Test
- QC Lot
- Event Type
 - Both the default library and custom event types will display under here for selection
 - The default library contains the following event types:
 - Calibration Error
 - Calibration Performed
 - Instrument Maintenance
 - System Reagent(s) Changed
 - Preanalytical Error
 - Analytical Error
 - Short Sample
 - Lot Change
 - Operator Error
 - Control Material
 - Contamination
- Date Time
- Event Comment
 - A maximum of 100 characters may be inputted in this field

Select **SAVE** to log the new event. This will populate on the “Event/Action Log” page.

Adding New Events from the Levey-Jennings tab

Navigate to **Review > Levey-Jennings**. Left click anywhere on the Levey-Jennings Chart.



Select the “New Event” option and a pop-up will display.

Event/Action log

Instrument

THERMO SCIENTIFIC INDIKO Plus, 123456789 (Chemistry) ▾

Test

A1c ▾

QC Lot

< ALL > ▾

Event Type

< Uncategorized > ▾

Date Time

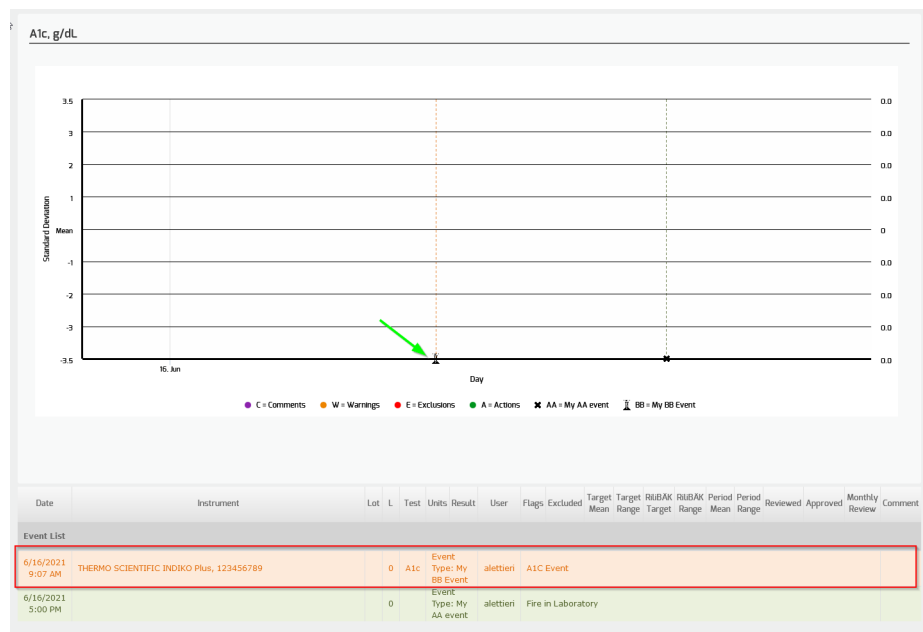
6/16/2021 11 : 20 : 02 AM ▾

Event Comment

Cancel

SAVE >

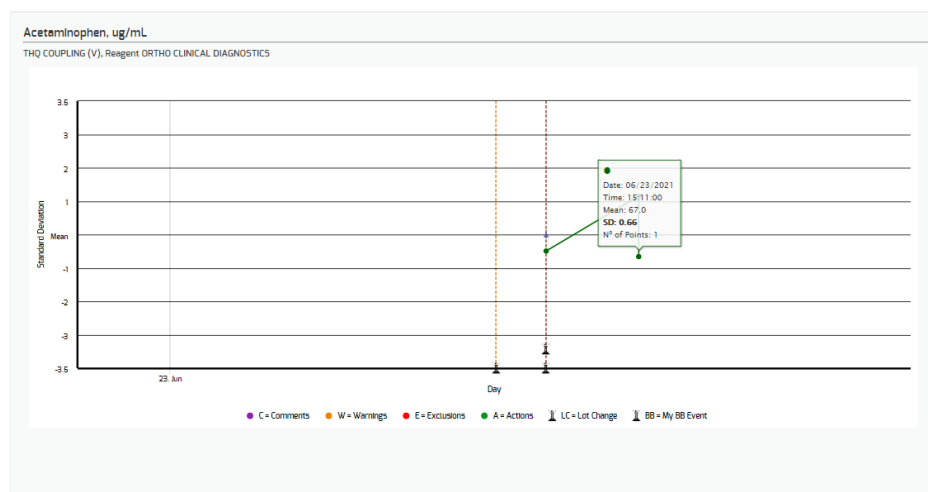
Input the information in each field and click **SAVE**. The new event will then display on both the Levey-Jennings chart and data table.



Viewing Events on the Levey-Jennings tab

Navigate to **Review > Levey-Jennings**. Events that have been logged will display on the Levey-Jennings chart and the Data Table.

Levey-Jennings Chart



Data Table

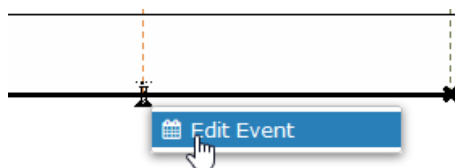
The “Show Events on LJ Chart” section is applicable only to events displayed on the Levey-Jennings Chart.

- “Show Events on LJ Chart” is selected: This displays all events for the selected profile on the Levey-Jennings chart.

Selecting the **SAVE PDF/PRINT** button on the bottom right of the screen will generate a PDF with the same selected parameters on the current Levey-Jennings page.

Editing Events on the Levey-Jennings Chart

To edit an existing event on the Levey-Jennings chart, left click on the event icon and select “Edit Event”.



Please note that only the event comment may be edited. The original event type cannot be modified.

Each time an event is edited, the previous comment is stored as part of the Audit Trail Report. Previously entered comments may be viewed in the “Event History” pop-up window, which is displayed by selecting on the icon in the data table (refer to image below).

Date	Instrument	Lot	L	Test	Units	Result	User	Flags	Excluded	Target Mean	Target Range	RU/BAK Target	RU/BAK Range	Period Mean	Period Range	Reviewed	Approved	Monthly Review	Comment
Event List																			
6/15/2021 3:38 PM			0				Chris Anchors			Chris Tsting									
6/16/2021 9:07 AM	THERMO SCIENTIFIC INDIKO Plus, 123456789		0	A1c		Event Type: My BB Event	alettieri			A1c Event Edited									
6/16/2021 5:00 PM			0			Event Type: My AA event	alettieri			Fire in Laboratory									

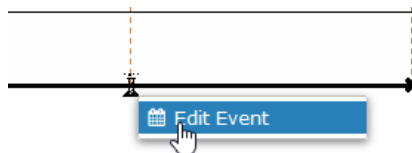
Display Only:

The “Event History” pop-up window will display all the historical information (i.e. User who edited the comment, time it was edited, etc.) for the given event.

Event History		
Instrument SIEMENS ATELLICA CH, CH01513 Atellica 1 (General)		
Test Carbon Dioxide (CO2)		
QC Lot 0DQ106, Chemistry-H Assayed 1		
Event Type New Reagent		
Date Time 1/23/2021 8:27:38 PM		
Event Comment New test		
Event	Date	By
Comment test	6/30/2021 4:42:24 PM	John Smith
TEsting	6/30/2021 4:42:51 PM	John Smith

Deleting Events on the Levey-Jennings Chart

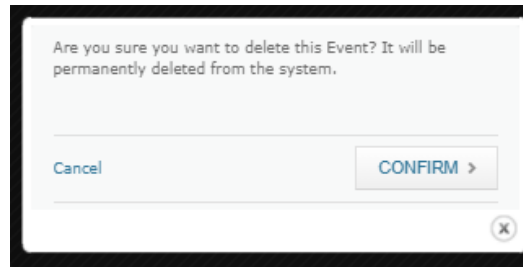
To delete an existing event on the Levey-Jennings chart, left click on the event icon and select “Edit Event”.



Proceed to select “DELETE” from the pop-up message.

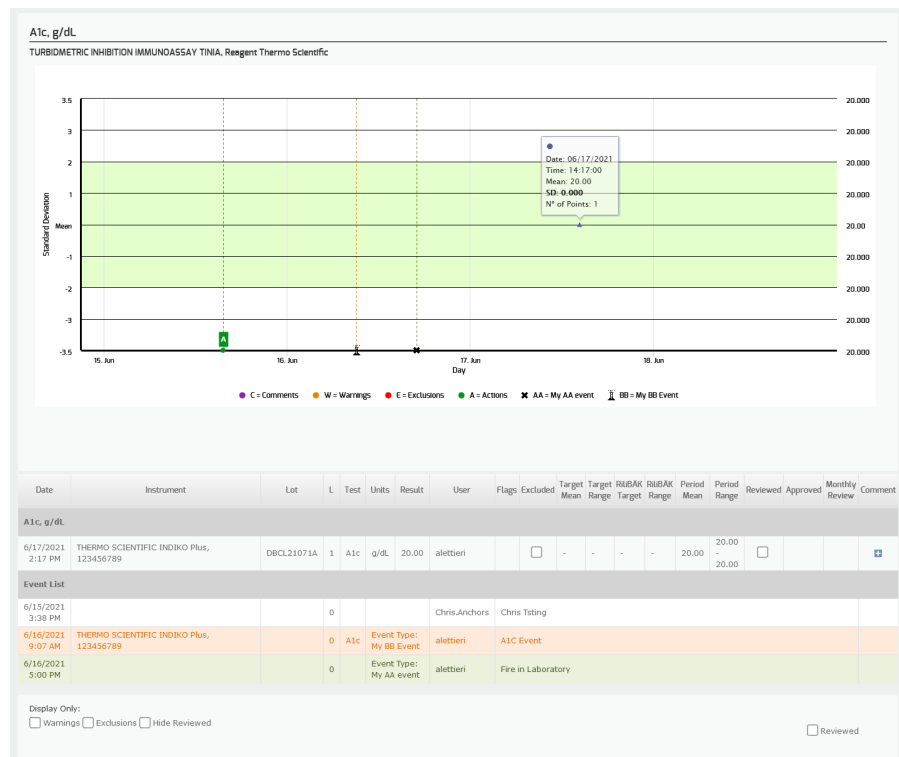
Event/Action log	
Instrument All	
Test All	
QC Lot All	
Event Type Network Issue	
Date Time 7/10/2021 9:24:49 AM	
Event Comment Network down	
Cancel	DELETE >
	SAVE >

Once “DELETE” is selected, a confirmation message will display to verify the deletion request.



Associating Events with Data Points

Navigate to **Review > Levey-Jennings**. Locate the data point to associate with a new event.



Left click on the data point and it will display a context menu with two options:

- Multiple Results – For editing/adding multiple data entries
- New Event – For adding a new event that is associated with the given data point



Clicking on “New Event” will display a pop-up with pre-filled information related to that given data point. Users may select an Event Type and add an Event Comment (refer to the image below).

Event/Action log

Instrument THERMO SCIENTIFIC INDIKO Plus, 123456789
(Chemistry)

Test A1c

QC Lot DBCL21071A, Liquid Diabetes 1

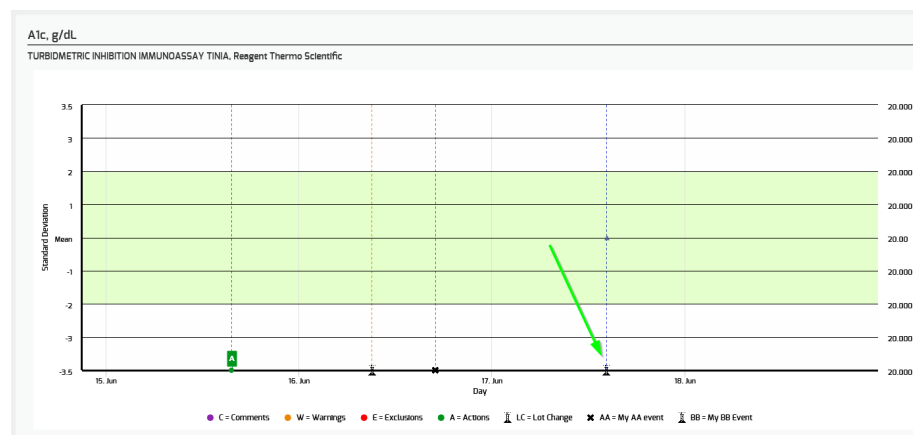
Event Type
LC - Lot Change

Date Time
6/17/2021 2:17:00 PM

Event Comment
Changed to lot AAA

Cancel SAVE >

This new event will display in the same location as the data point.




Since a single data point may have more than one event, additional events may be added by repeating the previous steps (i.e. Clicking on the data point and selecting “New Event”.

Please note that a maximum of 10 events may be associated with a single data point.

Viewing Events on the Data Table

The Data Table, on both the Levey-Jennings and Daily Data tabs, will display the logged events as follows:

- The events tied to the datapoint **always** appear below the datapoint, even when any given column is re-ordered.
- The events that are considered "Global events" (i.e. not associated with a datapoint) appear under the section titled “Event List”.
- The background and text color are defined when the event type was initially configured under **Settings > Event Type > ADD NEW**
- The event-specific icon (in the Levey-Jennings chart) is defined when the event type was initially configured under **Settings > Event Type > ADD NEW**

Date	Instrument	Lot	L	Test	Units	Result	User	Flags	Excluded	Target Mean	Target Range	RUBAK Target	RUBAK Range	Period Mean	Period Range	Reviewed	Approved	Monthly Review	Comment
A1c, g/dL																			
6/17/2021 2:17 PM	THERMO SCIENTIFIC INDIKO Plus, 123456789	DBCL21071A	1	A1c	g/dL	20.00	allettieri		<input type="checkbox"/>	-	-	-	-	20.00	20.00 - 20.00	<input type="checkbox"/>			
		Event Type: Lot Change				allettieri	Changed to lot AAA												
		Event Type: My AA event				allettieri	Another event tied to a datapoint												
Event List																			
6/15/2021 3:38 PM			0				Chris Anchors	Chris Titing											
6/16/2021 9:07 AM	THERMO SCIENTIFIC INDIKO Plus, 123456789		0	A1c		Event Type: My BB Event	allettieri	A1C Event											
6/16/2021 5:00 PM			0		Event Type: My AA event	allettieri	Fire in Laboratory												
Display Only: <input type="checkbox"/> Warnings <input type="checkbox"/> Exclusions <input type="checkbox"/> Hide Reviewed																			
																		<input type="checkbox"/> Reviewed	

Viewing the Event Tracking Report

All logged events may be reviewed as a report under the Reports tab. Ensure that “By Date Range” is selected before the “Event Tracking Report” is displayed.

Reports - Thermo Fisher Scientific - USA (55555) - ***TEST LAB***

Department: Chemistry

☐ By Month
 ☒ By Date Range
 ☐ Custom

From: 6/15/2021
 To: 6/18/2021
 Instrument: THERMO SCIENTIFIC INDICO Plus
 Product: < ALL >
 Lot: < ALL >

Levey-Jennings Report > Generate >
 Audit Trail Report > Generate >
 QC Summary Report > Generate >
 Point Data Submission Report > Generate >
 RABAK Data Submission Report > Generate >
 Event Tracking Report >

☐ By Instrument
 ☒ By Date

VIEW ALL > GENERATE ALL >

VIEW REPORT HISTORY > CONTINUE >

The Event Tracking Report may be viewed in two formats:

- **By Instrument** – This displays all the events grouped by instrument and then by test. All information matching the profile filter will be displayed in this report format.

Event Tracking Report (6/1/2021 - 7/23/2021)

Global Events

Date	Time	Event Type	Action
7/10/2021	9:24 AM	Network Issue	Network down

Instrument: SIEMENS ATELLICA CH, CH01513 Atellica 1 (General)

Test: Carbon Dioxide (CO2)

Date	Time	Lot#	Event Type	Action
7/7/2021	1:59 AM	0DQ306	New Reagent	New Reagent in use

- **By Date** – This displays a format similar to that of the Audit Trail Report (i.e. single table, ordered by date).

Event Tracking Report (6/1/2021 - 7/23/2021)						
Date	Time	Instrument	Lot#	Test	Event Type	Action
7/7/2021	1:59 AM	SIEMENS ATELLICA CH, CH01513 Atellica 1 (General)	0DQ306	Carbon Dioxide (CO2)	New Reagent	New Reagent in use
7/10/2021	9:24 AM	***	***	***	Network Issue	Network down

Please note that the Audit Trail Report will also track events that have been logged.

Fixes

3. **Fixed an issue where data was not displaying on the Levey-Jennings graph when the apostrophe punctuation mark was inputted in the Comments section.**

Previously, the application would not display data on the Levey-Jennings graph when an apostrophe punctuation mark was inputted in the Comments. This issue has now been rectified so that apostrophes may now be accepted in the Comments field.

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 lablink.gap@thermofisher.com.

Sincerely,



Chris Anchors

Technical Product Manager

Clinical Diagnostics Division

Thermo Fisher Scientific