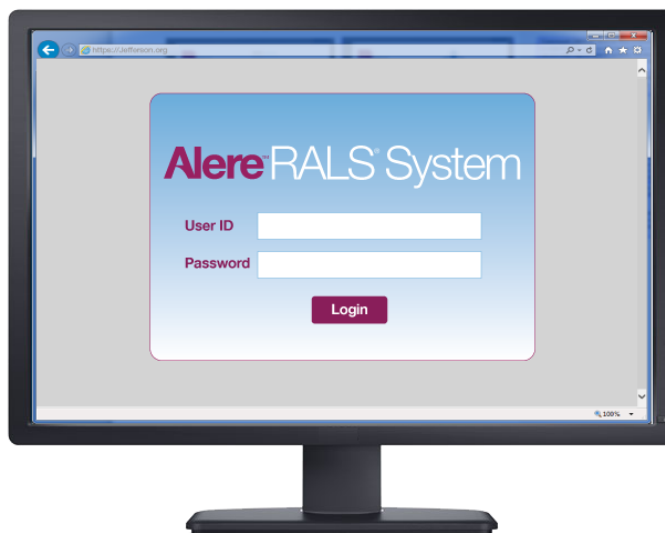


Release Summary for Alere RALS® System



Version 5.12

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Alere RALS® System Updates

Updated:

Repeat Tests

New evaluation criteria and evaluation processing – along with a new flag – have been added to the Alere RALS® System to allow further options for handling repeat tests.

Note: If the new criteria is not enabled in an Evaluation Criteria set, repeat test behavior remains the same. With one exception, a result might receive the new *Repeat Test Already Sent* flag, described below.

The following use cases demonstrate the new Repeat Test functionality.

Evaluation Criteria

<input type="checkbox"/> Evaluate Patient ID	
<input checked="" type="checkbox"/> Evaluate Operator ID	
<input checked="" type="checkbox"/> Evaluate Operator Certification	
<input checked="" type="checkbox"/> Evaluate Flagged Comments	
<input type="checkbox"/> Flag All Results From This Location	<input type="checkbox"/> Evaluate Order ID
<input checked="" type="checkbox"/> Evaluate Repeat Tests (repeat interval mins) 10	<input type="checkbox"/> Evaluate Invalid Cartridge Lot Numbers
<input type="checkbox"/> Evaluation Delay Period (mins) <input type="text"/>	<input type="checkbox"/> Evaluate Cartridge Lot Mfg Expiration Date
<input type="checkbox"/> Release Most Recent Repeat to LIS	

Evaluation Criteria set with Evaluate Repeat Test enabled but the new criteria not enabled

Use Case 1:

Evaluate Repeat Tests – 10 minutes. If only this is checked (and not the other 2 repeat criteria option below it) then it behaves same as < 5.12:

- The test is held as soon as it hits the Evaluator for 10 minutes.
- During this 10-minute Hold Period, if a test that meets the Repeat Definition (same patient and sample type that was run within 10 minutes of the test being held) hits the Evaluator, then all tests will flag for *Repeat Test*.
- If the test being held is found to be the repeat of a test that has previously hit the Evaluator (but not still being held by Evaluator) then only this test will flag for *Repeat Test* (regardless of whether it was the 1st or 2nd or even 3rd test).
 - This test will also be flagged for *Repeat Test Already Sent*, which is a new flag added in 5.12.

Evaluation Criteria

☐ Evaluate Patient ID
 ☒ Evaluate Operator ID
 ☒ Evaluate Operator Certification
 ☒ Evaluate Flagged Comments
 ☐ Flag All Results From This Location
 ☐ Evaluate Order ID
 ☒ Evaluate Repeat Tests (repeat interval mins) 10
 ☐ Evaluate Invalid Cartridge Lot Numbers
 ☒ Evaluation Delay Period (mins) 3
 ☐ Evaluate Cartridge Lot Mfg Expiration Date
 ☒ Release Most Recent Repeat to LIS

New evaluation criteria enabled

Evaluate repeat tests – 10 minutes.
 Evaluate Delay Period – 3 minutes
 Release Most Recent Repeat to LIS

Use Case 2:

Evaluate Delay – 3 minutes. If checked, then the Hold Period now becomes 3 minutes, rather than the 10 minutes entered in Evaluate Repeat Tests. In this example, the test is held for 3 minutes as soon as it hits the Evaluator. This allows the test to get released sooner if a 10-minute Hold Period is too long for the users. During this 3-minute period, same rules apply:

- If a test that meets the Repeat Definition (same patient and sample type that was run within 10 minutes of the test being held) hits the Evaluator, then all tests will flag for *Repeat Test*.
- If the test being held is found to be the repeat of a test that has previously hit the Evaluator (but not still being held by Evaluator) then only this test will flag for *Repeat Test* (regardless of whether it was the 1st or 2nd or even 3rd test). This test will also be flagged for *Repeat Test Already Sent*.

Use Case 3:

Release Most Recent Repeat to LIS. If checked:

- The Alere RALS® System will attempt to upload to LIS the most recent test in a series of repeated tests, if none of the tests in the series has already uploaded.
- If the Evaluator identifies that a test is part of a series of repeats where any test in the series has already uploaded, then the most recent will not upload, but will be flagged for *Repeat Test Already Sent*.
- If Repeat Test is configured to Send to LIS in Flag Configuration, then all repeat tests will still upload to LIS regardless of this new selection.

New Features

Resend a Result

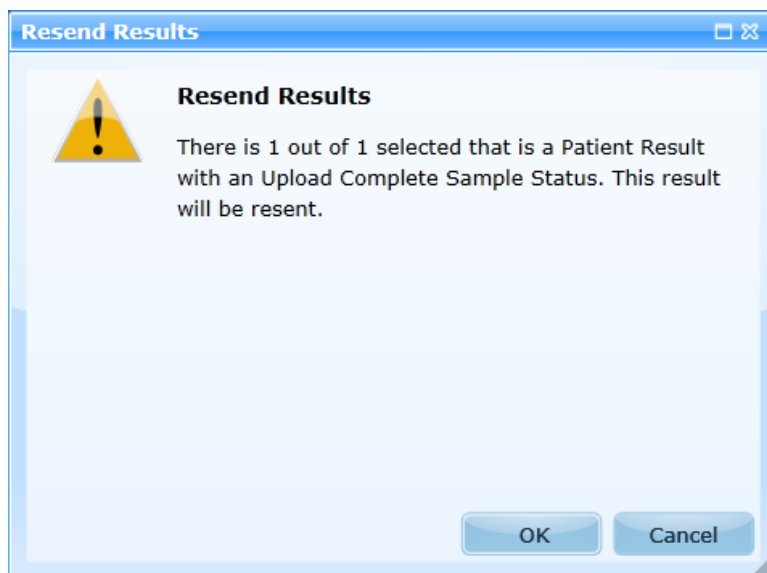
This new feature allows a user to send a patient result to the LIS that has already been sent to the LIS (which means it has a Sample Status of *Upload Complete*).

The screenshot shows the Alere RALS System interface. The top navigation bar includes 'All Institutions - MASSupport', 'Settings', 'Help', and 'Logout'. The main menu has tabs for 'Status', 'Results', 'Consumables', 'Operators', 'Locations', 'Tasks', 'Administration', and 'eQuiz'. The 'Results' tab is active, showing a 'Results Review' section. This section contains filters for 'Device Type' (set to 'ACCU-CHEK® Inform II'), 'Date Range' (01/16/2017 to 01/16/2017), 'Sample Type' (All Sample Types), 'Patient ID/Lot #', 'Location' (All Locations), 'Operator', 'Device ID', 'Sample Status' (All Sample Statuses), 'Flag' (All Flags), and 'Result Range (mg/dL)' (Glucose, Within/Outside). Below the filters are buttons for 'Apply', 'Review', 'Saved Notes', and 'Resend'. At the bottom, there is a table with columns: Date and Time, Patient ID / Lot #, Location, Operator, Result, Comment, Flags, Sample Status, Sample Type, Strip Lot #, Accession #, LIS Comment, and Device ID.

Access the Resend Dialog

Select any number of results in the list that you want to resend to the LIS. In order for the Alere RALS® System to actually resend a selected result though, it must have a Sample Status of *Upload Complete*.

Click the *Resend* button in the toolbar, or hover the cursor over one of the selected items, right click, and click on *Resend* in the pop-up menu. the Alere RALS® System describes which of your selected results is eligible to be resent.



If at least one result is eligible to be resent, you may click the *OK* button to resend. Only the eligible results from those selected will be resent.

A resent result is logged in edit logs as a Result Status change action (as its status is changed from Upload Complete to Upload Pending).

Whenever a resent result is successfully uploaded to the LIS (which means its Sample Status changes to Upload Complete), its Transfer Date & Time (available in its details) is updated to this new transfer.

Reassign a Result

This feature allows a user to assign a new Patient ID to a result that has already been sent to the LIS (which means it will have a Sample Status of *Upload Complete*). This process creates a new result (with the new Patient ID) and schedules it to be sent to the LIS (which means it will have a Sample Status of *Upload Pending*). The old result has its Sample Status changed to *Reassigned*. Only a single result can be selected. The Reassign option is presented in the Alere RALS® System for any selected results, however the Alere RALS® System will prompt the user to make a valid selection (i.e., a single patient result with a Sample Status of *Upload Complete*).

The screenshot shows the Alere RALS System interface. The top navigation bar includes 'All Institutions - MASSupport', 'Settings', 'Help', and 'Logout'. The main menu has tabs for 'Status', 'Results', 'Devices', 'Consumables', 'Operators', 'Locations', 'Tasks', 'Administration', and 'eQuiz'. The 'Results' tab is active, showing sub-tabs: 'Flagged Results', 'Results Review', 'Results Management', 'Levey-Jennings', 'Linearity', 'Proficiency Review', and 'Enter Manual Result'. The 'Results Review' sub-tab is selected. The page contains several input fields and dropdown menus for filtering results: 'Device Type' (set to 'ACCU-CHEK® Inform II'), 'Date Range' (01/16/2017 to 01/16/2017), 'Sample Type' (All Sample Types), 'Patient ID/Lot #', 'Location' (All Locations), 'Operator', 'Device ID', 'Sample Status' (All Sample Statuses), 'Flag' (All Flags), and 'Result Range (mg/dL)' (Glucose, Within/Outside). A toolbar at the bottom includes buttons for 'Apply', 'Review', 'Saved Notes', 'Resend', 'Reassign', and 'Recall', along with icons for printing, email, and other functions. A table at the bottom displays columns for 'Date and Time', 'Patient ID / Lot #', 'Location', 'Operator', 'Result', 'Comment', 'Flags', 'Sample Status', 'Sample Type', 'Strip Lot #', 'Accession #', 'LIS Comment', and 'Device ID'.

Access the Reassign Result Page

Select a single patient result in the list that you want to reassign. The selected result must have a Sample Status of *Upload Complete* in order to be reassigned.

Click the *Reassign* button in the toolbar, or hover the cursor over the target item, right click, and click *Reassign* in the pop-up menu. If the result is eligible to be reassigned, the Alere RALS® System will take you to the Reassign Result page:

The screenshot shows the Alere RALS System interface with the 'Patient Search' dialog box open. The top navigation bar is the same as the previous screenshot. The 'Results' tab is active, and the 'Reassign Result' sub-tab is selected. The dialog box has a 'Search' button and a table with columns for 'Name', 'Sex', 'DOB', 'Medical Record', and 'Institution'. Below the table are 'Apply' and 'Reassign' buttons. A table at the bottom displays columns for 'Id', 'Id Type', 'Physician', 'Service Name', 'Service Id', and 'Start Date and Time'.

Click the **Search** button to display the **Patient Search** dialog. Narrow down your patient list by searching by First Name, Last Name, Date of Birth, Gender, Patient ID (specifying type), and/or Institution. Click **Apply** to display results.

Patient Search

First Name Last Name

Date of Birth 15 Gender

ID Type Medical Record Patient ID

Institution Default Institution

Apply

Name	Gender	Date of Birth	Institution	Medical Record
Evergreen^Erik	M	06/01/1990	Default Institution	MR0327710977
Friberg^Marshall	M	12/05/2009	Default Institution	MR2007513916
Kahle^Kristine	F	06/08/1994	Default Institution	MR1019927285
Maxwell^Justin	M	01/09/1993	Default Institution	MR0653227023
Reynolds^Oliver	M	07/23/1936	Default Institution	MR0907203438
Thiel^Patrick	M	07/28/1937	Default Institution	MR1723381315

Page Size 20 Total Records: 10

Page 1 of 1

OK **Cancel**

Choose a patient and click **OK**. The **Reassign Result** page is displayed again. All ID numbers associated with the patient are now displayed in the lower grid along with all open orders associated with that patient.

Status **Results** **Devices** **Consumables** **Operators** **Locations** **Tasks** **Administration** **eQuiz** www.RALS.com

Flagged Results **Results Review** Levey-Jennings Linearity View Orders

To Results Review **Reassign Result** Date and Time: 07/06/2015 01:41:42 PM Patient ID: AN1319459774 Result # 6109

Patient

Search

Name	Sex	DOB	Medical Record	Institution
Bachman^Kristine	F	07/06/1982	MR0869584126	Default Institution

Apply **Reassign**

Id	Id Type	Physician	Service Name	Service Id	Start Date and Time
MR0869584126	Medical Record	White, Rick			
AN0650927536	Account	White, Rick			
XN0042014552	Episode	White, Rick			

Select the row that contains the ID you wish to assign to the result and click *Reassign* to execute that assignment.

A confirmation window pops up. Click **OK** to confirm the assignment or **Cancel** to return to the **Result Reassignment** page. If you click OK, the Alere RALS® System creates a new result in the system with all the data from the original result except with the new **Patient ID**. Also, its **Sample Status** is set to *Upload Pending* until the Alere RALS® System is able to send it to the LIS. The original result's **Sample Status** is set to *Reassigned* so that it can be easily identified with the Sample Status filter.

When a result is reassigned, 2 entries are added to the results edit logs:

- 1) A Result Status Change Action on the original result because its Sample Status changed from Upload Complete to Reassigned.
- 2) An Add Change Action for the new result.

On the Results Review page, you can identify 2 entries that were generated by the same Reassign action if their Date and Time match and their Device ID match.

Whenever a reassigned result is successfully uploaded to the LIS (which means its Sample Status changes to Upload Complete), its Transfer Date & Time (available in its details) is updated to this new transfer.

When using Result Reassignment, the original result will not be transferred to the LIS. If further updates to the original result are required, use Result Recall.

Recall a Result

This feature allows a user to modify a patient result that has already been sent to the LIS by changing the values of specific analytes to predefined values. Available Value Options are set up by Alere Informatics implementation (in partnership with the customer). The selected result must have a Sample Status of *Upload Complete* or *Reassigned*. This process will send the result to the LIS again.

The Recall feature is typically used to indicate that a result or Result Value previously sent is now invalid or not applicable. Using Recall removes the unit of measure associated with the Result Value along with any flags. A recalled Result Value is also made unavailable for any static calculations. The Recall result feature functionality will need to be confirmed with each site's individual LIS system.

Alere RALS System All Institutions - MASSupport Settings Help Logout

Status Results Devices Consumables Operators Locations Tasks Administration eQuiz www.RALS.com

Flagged Results **Results Review** Results Management Levey-Jennings Linearity Proficiency Review Enter Manual Result

Device Type: ACCU-CHEK® Inform II Date Range: 01/16/2017 To 01/16/2017 Sample Type: All Sample Types

Patient ID/Lot #: Location: All Locations Operator:

Device ID: Sample Status: All Sample Statuses Flag: All Flags

Result Range (mg/dL): To: Within Outside

Glucose

Apply Review Saved Notes Resend Reassign Recall

Date and Time	Patient ID / Lot #	Location	Operator	Result	Comment	Flags	Sample Status	Sample Type	Strip Lot #	Accession #	LIS Comment	Device ID
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Access the Resend Dialog

Select a single patient result in the list that has analyte values you want to change. The selected result must have a Sample Status of *Upload Complete* or *Reassigned*.

Click the *Recall* button in the toolbar, or hover the cursor over one of the desired item, right click, and click on *Recall* in the pop-up menu. The Alere RALS® System pops up the Result Recall window.

Result Recall

Value Options: **TNP**

☒ All

Analyte	Old Value
<input checked="" type="checkbox"/> Flu A	Negative
<input checked="" type="checkbox"/> Flu B	Negative

Note: Save For Later: ☐

Save Cancel

Select the analytes whose value you wish to change by clicking their checkboxes. You may select multiple analytes if the result has more than one. You may select every analyte by clicking *All*. At least one selected analyte is required.

In the Value Options drop down menu, select the value you wish to assign to the selected analytes. This list is populated with the values listed in the Result Recall Value Options that were set up by Alere Informatics implementation (in partnership with the customer). The same value will be applied to all selected analytes.

Assign a note that will accompany each changed value in the message to the LIS. You can either select a saved note in the Note drop down list or enter your own note as text. Note is required.

- If you enter your own note, you can check the *Save For Later* checkbox to put that entry in the Note drop down for future results.
- *Text Option '[O]'*: The Alere RALS® System allows you to include the analyte's previous value in the note. Just insert *[O]* (capital 'O' enclosed in brackets) in the text where you want the previous value to appear, and the note associated with each selected analyte will contain that analyte's previous value.
- *Text Option '[E]'*: Normally, the note you assign will be sent to the LIS as a single piece of information. You have the option - if your LIS would need it - to cause the note to be uploaded to the LIS in multiple segments. You enter *[E]* (capital 'E' enclosed in brackets) between each desired segment in your note.

To complete the Result Recall, click 'Save'.

Flagged Results Grid

The following columns have been added: Patient Name, Patient DOB, Patient Gender, Last Review Date, Last Reviewer, and Last Review

Note: The new columns are not displayed by default.

The screenshot shows the 'Flagged Results' grid in the Alere RALS System. The top navigation bar includes 'Status', 'Results', 'Devices', 'Consumables', 'Operators', 'Locations', 'Tasks', 'Administration', and 'eQuiz'. The 'Results' tab is active, and the 'Flagged Results' sub-tab is selected. The grid displays columns: Date and Time, Patient ID, Location, Last Review Date, Last Reviewer, Last Review Note, Patient DOB, Patient Gender, Patient Name, Glu, Operator, and Comment. The form includes filters for Device Type (Nova StatStrip® GLU), Date Range (01/04/2016 to 12/13/2016), Location (All Locations), and Reason For Failure (All Failures). Action buttons include Apply, Review, Edit, Upload to LIS, Override, Do Not Upload, and View ADT Events.

Results Review Grid

The following columns have been added: Patient Name, Patient DOB, Patient Gender

Note: The new columns are not displayed by default.

The screenshot shows the 'Results Review' grid in the Alere RALS System. The top navigation bar includes 'Status', 'Results', 'Devices', 'Consumables', 'Operators', 'Locations', 'Tasks', 'Administration', and 'eQuiz'. The 'Results' tab is active, and the 'Results Review' sub-tab is selected. The grid displays columns: Date and Time, Patient ID / Lot #, Patient Name, Patient DOB, Patient Gender, Flags, Location, Comment, Supervisor ID, Operator, Glu, Sample Status, Sample Type, and Acc. The form includes filters for Device Type (Nova StatStrip® GLU), Date Range (01/16/2017 to 01/16/2017), Location (All Locations), Sample Status (All Sample Statuses), Sample Type (All Sample Types), Operator, Flag (All Flags), and Specimen Type (All). Action buttons include Apply, Review, Saved Notes, Resend, Reassign, and Recall.

Operators Grid

The following columns have been added: Phone, Fax, and Memo.

Note: The new columns are not displayed by default.

The screenshot shows the 'Operators' grid in the Alere RALS System. The top navigation bar includes 'Status', 'Results', 'Devices', 'Consumables', 'Operators', 'Locations', 'Tasks', 'Administration', and 'eQuiz'. The 'Operators' tab is active, and the 'Operators' sub-tab is selected. The grid displays columns: Name, ID, Authority Level, Home Location, Institution, Role, Message, Login Locked, Operator No, Phone, Fax, Memo, Is Observer, and Acc. The form includes filters for Operator, Home Location (All Locations), Assigned Location (All Locations), and Device Type (ACCU-CHEK® Inform II). Action buttons include Apply, Add, Edit, Remove, and Restore.

Add Operators Dialog

A Memo field is now available on the Add Operators page. It contains up to 255 characters.

Add Operator

Name Home Institution

Operator ID Home Location

Authority Level: Phone Number

System Role: Email Address

☐ Supervisor Fax Number

☐ Observer LIS Memo

☐ Login Locked Memo

Assigned Locations

> ☐ Default Institution

Device Certifications

Device	Initial Certification	Last Certification	Certification Expi
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Patient ADT Page

The full patient name is displayed on the Patient ADT Events page. In addition to first and last name, the suffix and middle name are displayed if available.

Alere RALS System All Institutions - MASSupport Settings Help Logout

Status Results Devices Consumables Operators Locations Tasks Administration eQuiz www.RALS.com

Reports Edit Logs Patient ADT Events ADT Assignments Profiles Import HL7 Log

Name: Evergreen, Olga Y. Date of Birth: 10/20/1955 Gender: F Institution: Thomas Jefferson Hospital

ADT Location	Location	Event Time	Event Type	Medical Record	Account	Episode	Visit	Physician	Outpatient
Unit 4-01	Jefferson 4	12/07/2016 12:01:55 PM	A01	MR1157925031	AN1023767351	XN2128963521	VT0481059179	DX1598661399^Mitchell Green^Yennifer	No

Abbott i-STAT® 1

Added new i-STAT Quality Check Code by Operator Only. This new report is identical to the existing i-STAT Quality Check Code by Operator report except the new report excludes the location grouping. Operators in the new report are only grouped by institution.

Nova Biomedical StatStrip® GLU

When using the wireless Nova ability to query a patient, discharged patients are no longer included in the lookup.

The Alere RALS® System Fixes

Accriva Diagnostics Hemochron Signature Elite® Lot Numbers

Cuvette lot numbers for the device may contain a "-" in the lot number. The Alere RALS® System validates the characters entered for lot numbers. Previously "-" was considered an invalid character. This causes an issue reviewing and editing the cuvette information. Now the only field validation for the devices is a requirement to not allow lower case characters.

Nova Biomedical Devices Tolerance Time

Tolerance is currently 30 seconds which can at the extremes cause the LIS to assess received results as "future". Tightening the limit makes this very unlikely and improves the overall alignment of device events with server time. Therefore, tolerance time is now 5 seconds.

Abbott i-STAT® 1 Value Types

Upgrading to 5.11 the LIS Names of i-STAT® 1 value types which were not available for selection in a profile caused the LIS interface to send an OBX message without a test code. The upgrade now only makes this modification on systems where i-STAT® 1 is not installed.

Abbott i-STAT® 1 Cal/Ver Test Results Report

Upgrading to 5.11 caused an issue where the filter options for i-STAT® 1 Cal/Ver Test Results report did not contain any values. This has been corrected and the filter options (Cartridge Lot, Device ID, Sample ID, Location, Operator ID) are now available.

Roche Diagnostic ACCU-CHEK® Inform II Levey Jennings View Report

In 5.11, a Levey Jennings report appeared with no data when a user selects View Report by Preview from the Levey Jennings grid. This issue has been fixed and the Levey Jennings report when viewed by Preview from the Levey Jennings grid will now display the appropriate data.

Levey Jennings View Report - Reagent Lot

Previous, when you Viewed the Levey Jennings Report, the Reagent Lot information was missing. If you Viewed the Levey Jennings Chart first then Viewed the Levey Jennings Report, the Reagent Lot information displayed. Now, the Levey Jennings report displays the reagent lot when accessed regardless of whether or not the Levey Jennings Chart was Viewed.