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Abbott Alinity Instrument Manager Result Review & Release


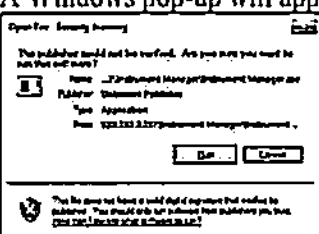
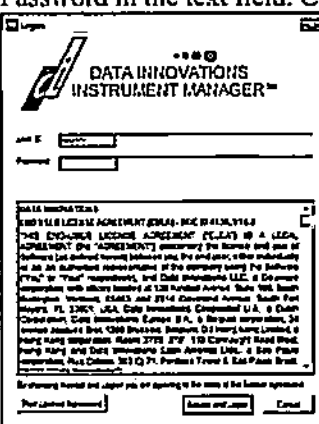

Purpose	This procedure is intended to provide instructions on how to review and release results in Data Innovations Instrument Manager for tests performed on Abbott Alinity ci-series analyzers.
Scope	This procedure is intended for trained Clinical Laboratory Scientists and Medical Laboratory Technicians.
Definitions	Autoverification: Autoverification refers to the automated release of clinical laboratory test or examination results to the medical record based on previously defined criteria and logic established, documented, and tested by the medical staff of the laboratory, from an electronically interfaced instrument.
Policy	<p>The list below states the policies followed by the organization:</p> <ul style="list-style-type: none"> • A licensed person must be physically present on site in the clinical laboratory whenever auto verification is being performed. They are responsible for the accuracy and reliability of results being reported. The operator is responsible for suspending auto verification in the event of a problem with the test method, analytical instrument, or auto verification criteria. • The operator must ensure that all quality controls are performed within the appropriate time intervals with acceptable results prior to performing patient testing. • If a problem is encountered with an instrument, the operator can turn off auto verification with menu options. When problems are resolved, auto verification may be turned back on. • Specimen Management Workspace In Instrument Manager is a workspace for results that meet the pre-established laboratory criteria of the middleware rules. The licensed laboratorian is required to investigate and do possible intervention prior to review/release. • An audit trail will be used to identify all individual who have entered or modified patient data or control files. If auto verification is used, the audit trail in the laboratory system should reflect that the result was verified automatically at a given date and time. • Instruments that have autoverification enabled must be validated initially and at least annually or when there is change to the system that could affect the autoverification logic and to confirm that algorithm decision rules are functioning properly.

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Abbott Alinity Instrument Manager Result Review & Release, Continued

Procedure:
Logging into
Instrument
Manager

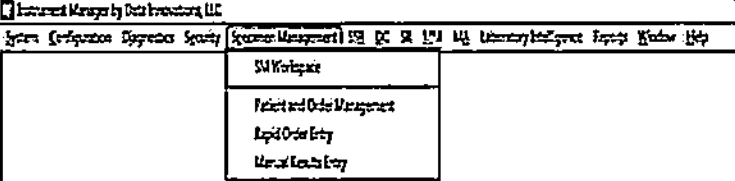
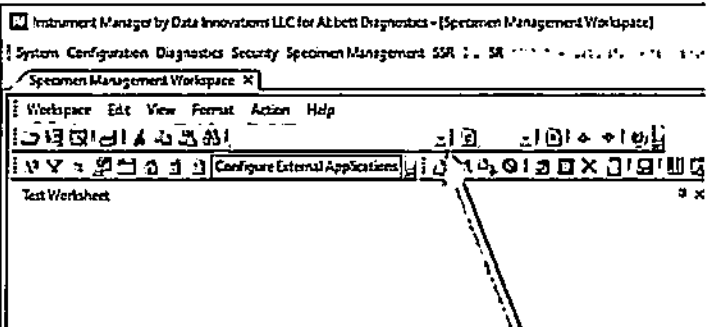
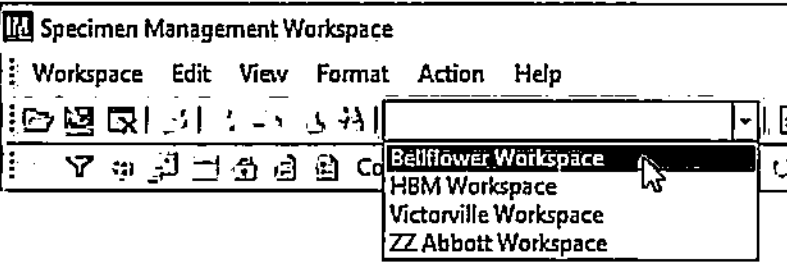
Follow the steps below to log into Instrument Manager:

Step	Action
1	Double-click the Instrument Manager  icon for your site.
2	A Windows pop-up will appear. Select Run. 
3	When the Logon window displays, enter your User ID (NUID) and Password in the text field. Click Accept and Logon.  <i>Note: For new users or after password reset, leave the password field blank and log in. The software will prompt you to set your password. If you have forgotten your password, please open a ServiceNow Directed Service Request to the NON IT SCAL LAB group.</i>
4	The application will open 

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Abbott Alinity Instrument Manager Result Review & Release, Continued**Procedure:
Accessing
Instrument
Manager
Workspace**

Follow the steps below to access the Instrument Manager workspace:

Step	Action
1	<p>From the Specimen Management menu, click SM Workspace.</p> 
2	<p>Once the workspace window open, proceed to click on the drop down menu</p> 
3	<p>Select from the drop-down menu, the instrument workspace for your site.</p> 

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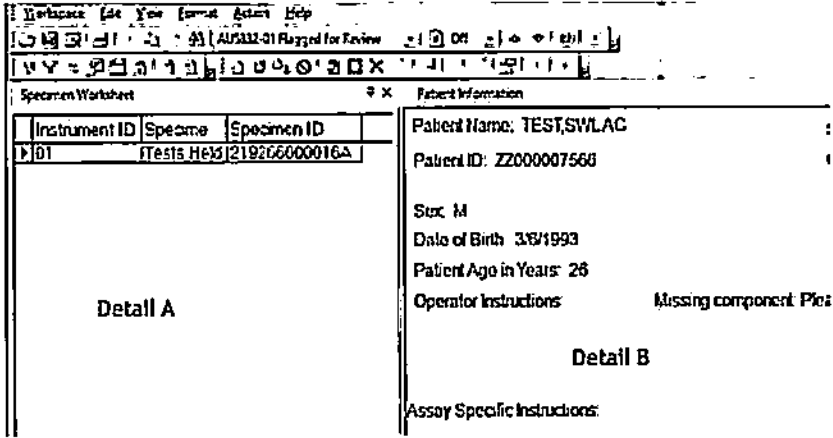
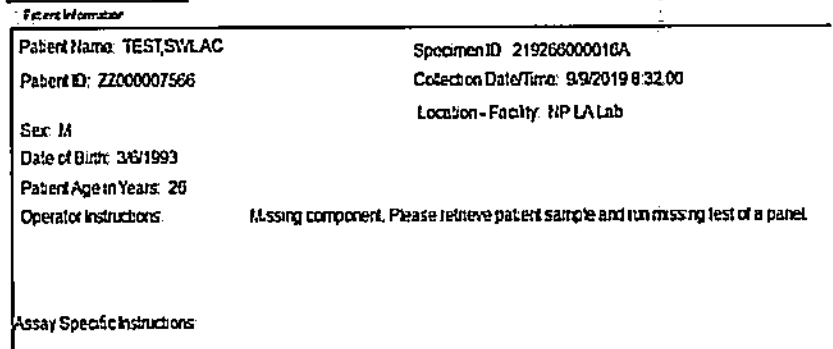
Kaiser Permanente
Medical Care Program
California Division - South

SCPMG Laboratory Systems
Chemistry
Procedure

Abbott Alinity Instrument Manager Result Review & Release, Continued

Procedure:
Instrument
Manager
Workspace
Result Review

Follow the steps below to review results in Instrument Manager:

Step	Action
1	<p>From the Specimen Worksheet pane, highlight the row with the accession number (see Detail A). The selected accession number will show a pane titled "Patient Information" (see Detail B). There will be Operator Instructions with the appropriate directives or information on the next steps to follow.</p>  <p>The screenshot shows the Instrument Manager interface. On the left is the 'Specimen Worksheet' pane with a table containing columns for 'Instrument ID', 'Specimen ID', and 'Specimen ID'. The first row is highlighted. On the right is the 'Patient Information' pane, which displays patient details: Patient Name: TEST, SWLAC; Patient ID: ZZ000007566; Sex: M; Date of Birth: 3/6/1993; Patient Age in Years: 26; Operator Instructions: Missing component: Please; Assay Specific Instructions.</p> <p>Detail A</p> <p>Detail B</p> <p>Detail B example (close-up):</p>  <p>The close-up screenshot shows the 'Patient Information' pane with the following details: Patient Name: TEST, SWLAC; Patient ID: ZZ000007566; Sex: M; Date of Birth: 3/6/1993; Patient Age in Years: 26; Operator Instructions: Missing component: Please retrieve patient sample and run missing test of a panel; Assay Specific Instructions.</p>


Continued on next page

Kaiser Permanente
Medical Care Program
California Division - South

SCPMG Laboratory Systems
Chemistry
Procedure

Abbott Alinity Instrument Manager Result Review & Release, Continued

Procedure:
Instrument
Manager
Workspace
Result Review,
continued

Instrument Manager Workspace Result Review						
Step	Action					
2	Investigate the cause(s) of the Flagged Result(s) such as "Error Codes" and "Error Names" and follow "Operator Instructions", if present in the Patient Information pane.					
	Test Code	Result	Units	Test Dilution	Error Code(s)	Error Name(s)
3	AGAP	Unable to Calc...			Flagged	Flagged
	NTBILI	18.0	mg/dL	STANDARD	cl_HFlaggedFlagged	PANIC SZ c...
	BUN	<3	mg/dL	STANDARD	Flagged	Flagged
	CO2	5	mEq/L	STANDARD	cl_FlaggedFlagged	PANIC cl_Re...
	CL	51	mEq/L	STANDARD	Flagged	Reflow
	CLOT	Clot?			FLAGGEDFlagged	Verify clot st...
	FBS	0	mg/dL	STANDARD	cl_FlaggedFlagged	PANIC cl_Re...
	H	0	Index		Flagged	Flagged
	I	9.6	Index		Flagged	Flagged
	L	-11	Index		Flagged	Flagged
	K	130	mEq/L	STANDARD	cl_IV CONTAMFlagged	PANIC cl_CH
	NA	110	mEq/L	STANDARD	cl_CLOTFlaggedFlagged	PANIC cl_CL
	<input checked="" type="checkbox"/> Release function <input checked="" type="checkbox"/> Reject function					
	Refresh the workspace by pressing the Refresh  button. If no other accession number populates the workspace. All results that filter through the rules cascade and do not hit any of the rules algorithms will Auto verify to our LIS (Cerner).					
4						

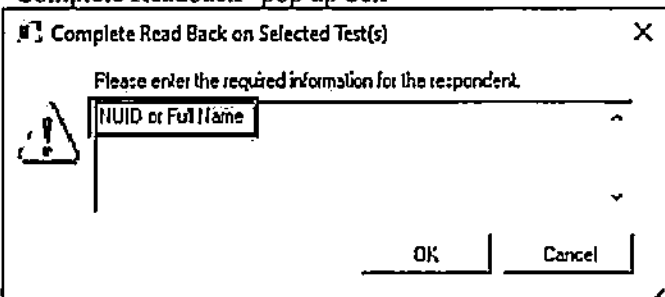

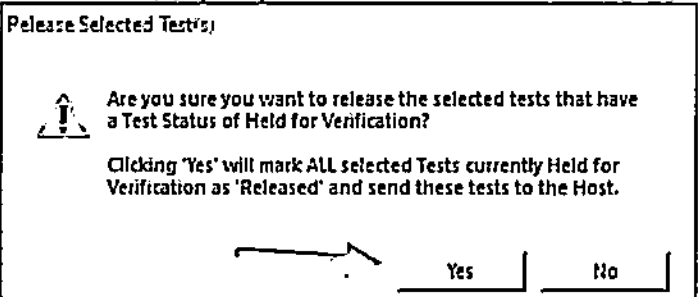
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Chemistry
Procedure

Abbott Alinity Instrument Manager Result Review & Release, Continued

Procedure:
Critical Result
Reporting,
continued

Step	Action																																																																
3	<p>Enter the NUID or Full Name of the notified personnel in the "Complete Readback" pop up box</p> 																																																																
4	<p>Verify the "Readback" process was successfully recorded by confirming change in color coding (yellow → light blue) of the critical result entry.</p> <p>Verify that all three readback columns are completed, see "red arrows" on the image below:</p> <table border="1"> <thead> <tr> <th>Test Code</th><th>Result</th><th>Error Code(s)</th><th>Error No.</th><th>Test Comment(s)</th><th>Read Back</th><th>Read Back Comm.</th><th>Read Back Date/TL</th></tr> </thead> <tbody> <tr> <td>2</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>H</td><td>1</td><td>HOLD</td><td>OTHER</td><td></td><td></td><td></td><td></td></tr> <tr> <td>H</td><td>229</td><td>HOLD</td><td>OTHER</td><td></td><td></td><td></td><td></td></tr> <tr> <td>HL</td><td>21</td><td>HOLD</td><td>OTHER</td><td></td><td></td><td></td><td></td></tr> <tr> <td>NDDBL</td><td>11.7</td><td>HOLD</td><td>OTHER</td><td></td><td></td><td></td><td></td></tr> <tr> <td>NTBLL</td><td>11.1</td><td>CHL</td><td>PANIC</td><td>Sample Identity not 0734011</td><td>Dr Nick Peters</td><td></td><td>11/5/2024 7:25:20 AM</td></tr> </tbody> </table>	Test Code	Result	Error Code(s)	Error No.	Test Comment(s)	Read Back	Read Back Comm.	Read Back Date/TL	2																H	1	HOLD	OTHER					H	229	HOLD	OTHER					HL	21	HOLD	OTHER					NDDBL	11.7	HOLD	OTHER					NTBLL	11.1	CHL	PANIC	Sample Identity not 0734011	Dr Nick Peters		11/5/2024 7:25:20 AM
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5	<p>Press the "Release" button  and acknowledge the "Release Selected Test(s)" prompt box to send results to Cerner (LIS)</p> 																																																																

Continued on next page

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Chemistry
Procedure

Abbott Alinity Instrument Manager Result Review & Release, Continued

Procedure: Safe
Zone Critical
Result
Reporting

Follow the steps below when encountering a Safe Zone critical result:

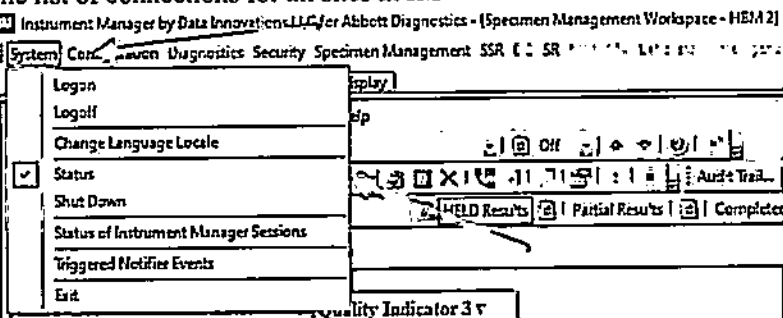
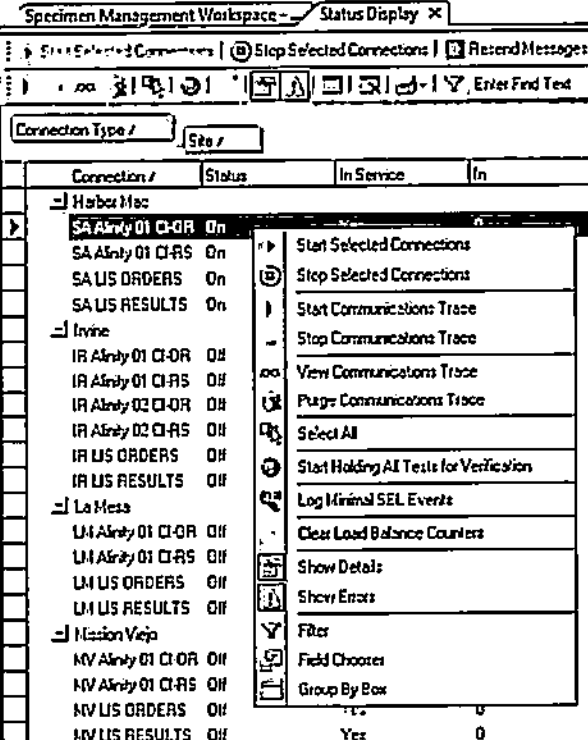
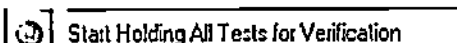
Step	Action																																																																										
1	<p>From the Test Worksheet, select the color coded "Critical Result" entry with corresponding "Operator Instructions" for the critical "Safe Zone" verification steps</p> <p>Specimen Worksheet</p> <table border="1"> <thead> <tr> <th>Specimen ID #</th><th>Priority</th><th>Patient Name</th><th>Rack</th><th>Requested Date/Time</th><th>Specimen Site</th><th>Quality Enter 4</th></tr> </thead> <tbody> <tr> <td>210010101</td><td>R</td><td>SAFEZONE/MDI L</td><td>FL</td><td>12/22/24 9:32:59 AM</td><td>Biochem/Misc</td><td>FLAGGED</td></tr> </tbody> </table> <p>Test Worksheet</p> <table border="1"> <thead> <tr> <th>Connection Name</th><th>Test Name</th><th>Test Code</th><th>Result</th><th>Units</th><th>Result Status</th><th>Err</th><th>Test Decision</th></tr> </thead> <tbody> <tr> <td>SAAlinity 01 CIRS</td><td>AGAP</td><td>AGAP</td><td>Facile to Calc</td><td>g/dL</td><td>F</td><td></td><td></td></tr> <tr> <td>SAAlinity 01 CIRS</td><td>Bilirubin Total Serum</td><td>NTBIL</td><td>0.2</td><td>mg/dL</td><td>F</td><td></td><td>STANDARD</td></tr> <tr> <td>SAAlinity 01 CIRS</td><td>Blood Urea Nitrogen</td><td>BUN</td><td><3</td><td>mg/dL</td><td>F</td><td></td><td>STANDARD</td></tr> </tbody> </table> <p>Patient Information</p> <p>Patient Name: SAFEZONE/MDI L Specimen Type:</p> <p>Patient ID: Z100010101 Ordering Physician: JDEMAN/TEST,</p> <p>Date of Birth: 12/22/24 3:09:53 AM</p> <p>Sex: M Location - Facility: NPBBM Lab</p> <p>Operator Instructions: - Verify sample identity and integrity. Follow Critical Call Notification procedure. Press Complete Read Back and Enter the NUD (or Full Name) of the notified person(s) in the Complete Read Back pop-up box. Highlight the accession number from the Specimen Worksheet page and press the Release function. For Safe Zone: Verify patient age in Cerner. Check if the result is critical. If critical, follow</p> <p>Tests Scheduled to be Held</p> <table border="1"> <thead> <tr> <th>Connection Name</th><th>Instrument ID</th><th>Test</th><th>Description</th></tr> </thead> <tbody> <tr> <td>SAAlinity 01 CIRS</td><td>SAALN1C01</td><td>AGAP</td><td>AGAP</td></tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Err</th><th>Error Code(s)</th><th>Error Name(s)</th><th>Test Connection(s)</th><th>Test Instrument ID</th><th>Instrument ID</th><th>Rack</th><th>Facile</th><th>Read Back Status</th><th>Re</th></tr> </thead> <tbody> <tr> <td>0</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table> <p>SAAlinity 01 CIRS F02-01 0</p> <p>SAAlinity 01 CIRS F02-01 0</p> <p>SAAlinity 01 CIRS F02-01 0</p>	Specimen ID #	Priority	Patient Name	Rack	Requested Date/Time	Specimen Site	Quality Enter 4	210010101	R	SAFEZONE/MDI L	FL	12/22/24 9:32:59 AM	Biochem/Misc	FLAGGED	Connection Name	Test Name	Test Code	Result	Units	Result Status	Err	Test Decision	SAAlinity 01 CIRS	AGAP	AGAP	Facile to Calc	g/dL	F			SAAlinity 01 CIRS	Bilirubin Total Serum	NTBIL	0.2	mg/dL	F		STANDARD	SAAlinity 01 CIRS	Blood Urea Nitrogen	BUN	<3	mg/dL	F		STANDARD	Connection Name	Instrument ID	Test	Description	SAAlinity 01 CIRS	SAALN1C01	AGAP	AGAP	Err	Error Code(s)	Error Name(s)	Test Connection(s)	Test Instrument ID	Instrument ID	Rack	Facile	Read Back Status	Re	0									
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2	<p>Compare patient's age in IM and Cerner (LIS), check if the obtained result is also flagged as critical in Cerner.</p> <table border="1"> <thead> <tr> <th>If ...</th><th>Then ...</th></tr> </thead> <tbody> <tr> <td>Result is a true critical</td><td>Follow "Critical Result Reporting" procedure</td></tr> <tr> <td>Result is not a true critical</td><td>Release the result</td></tr> </tbody> </table>	If ...	Then ...	Result is a true critical	Follow "Critical Result Reporting" procedure	Result is not a true critical	Release the result																																																																				
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Abbott Alinity Instrument Manager Result Review & Release, Continued

Procedure:
Turning Auto
Verification Off

Follow the steps below to turn off autoverification in Instrument Manager:

Step	Action
1	<p>Go to the upper lefthand corner, select "System" → "Status" to show the list of connections for all sites in IM</p> 
2	<p>Select the instrument that requires turn on/off by highlighting the analyzer and right click to show the menu.</p> 
3	<p>Select:</p> 

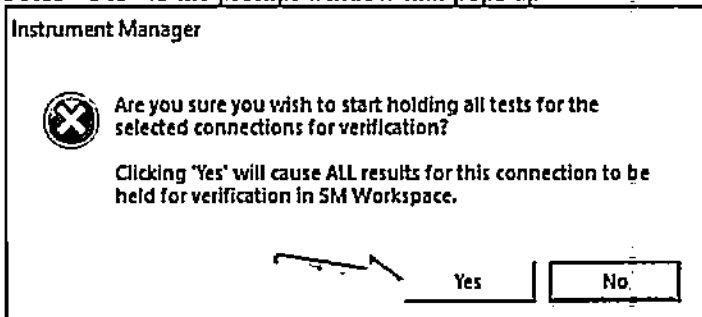
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Chemistry
Procedure

Abbott Alinity Instrument Manager Result Review & Release, Continued


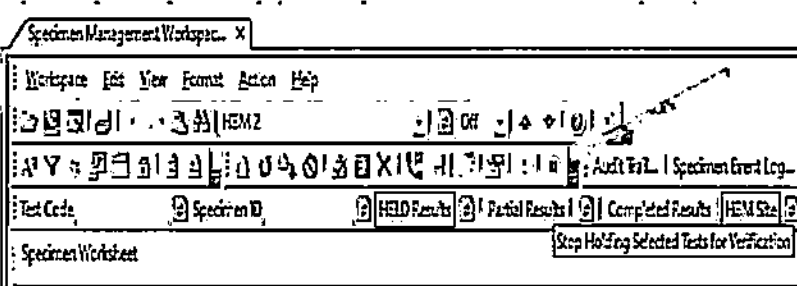
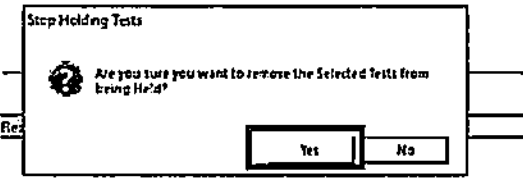
Procedure:
Turning Auto
Verification Off,
continued

Step	Action
4	<p>Press "Yes" to the prompt window that pops up</p> 
5	<p>All patient results will be held in the "Specimen Management Workspace" until all troubleshooting steps are completed and autoverification can be turned back "On"</p>

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Abbott Alinity Instrument Manager Result Review & Release, Continued**Turning Auto
Verification On**

Follow the steps below to turn on autoverification in Instrument Manager:

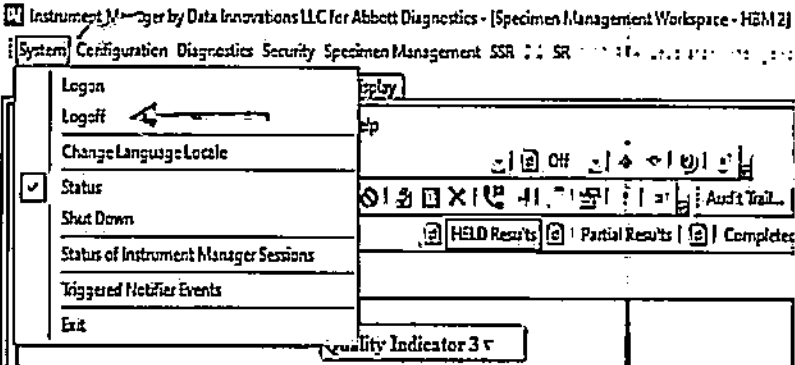
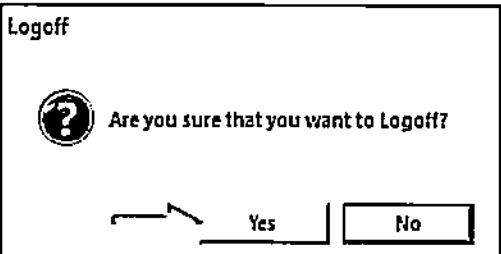
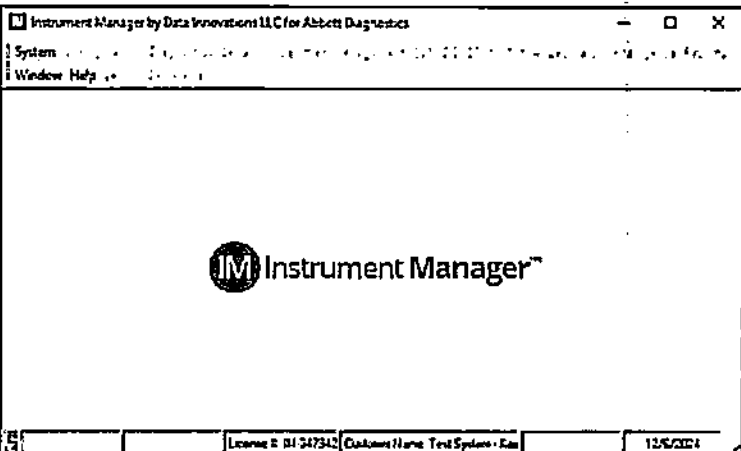
Step	Action
1	<p>Go to the "Specimen Management Workspace" and click on the  button to remove the hold.</p> 
2	<p>Select "Yes" on the Sop Holding Tests confirmation window.</p> 
3	<p>Patient testing may resume as applicable.</p>

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Abbott Alinity Instrument Manager Result Review & Release, Continued

Logging Off
Instrument
Manager

Follow the steps below to log off Instrument Manager:

Step	Action
1	<p>Click on "System" → "Logoff"</p> 
2	<p>Select "Yes" when the prompt window pops up to confirm the logoff request</p> 
3	<p>The system will return you to the log on screen</p> 

Continued on next page

Kaiser Permanente
Medical Care Program
California Division - South

SCPMG Laboratory Systems
Chemistry
Procedure

Abbott Alinity Instrument Manager Result Review & Release, Continued

Controlled Documents

The following controlled documents support this policy.

SCPMG QMS – 0025 Autoverification

Non-Controlled Documents

The following non-controlled documents support this policy.

- Data Innovations Instrument Manager User Guide

Regional Parent Document Reference Number: SCPMG-PPP-0625 Rev. 01

Signature Manifest

Document Number: RIV-PPP-1208

Revision: 01

Title: Abbott Alinity Instrument Manager Result Review and Release

Effective Date: 02 Jun 2025

All dates and times are in Pacific Standard Time.

Abbott Alinity Docs

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	23 May 2025, 07:53:29 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Talra (P161328)	CLIA Director	02 Jun 2025, 08:22:31 AM	Approved

