Policy:
Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS, where they are compared against laboratory-defined acceptance parameters. If the results fall within these defined parameters, the results are automatically released to patient reporting formats without any additional laboratory staff intervention. Any data that fall outside the defined parameters is reviewed by laboratory staff prior to reporting.
The technical staff reviews the results entry function to assure results that automatically crossed over from an interfaced instrument are reviewed and finalized (accepted) as per protocol. The results entry function is where results that did not get autoverified will be displayed.

A. Autoverification Process

1. Autoverification is validated prior to implementation. Refer to #5 for the validation parameters tested. The Medical Director approves the autoverification process for the specific instrumentation.
2. List of instrumentation validated for autoverification is located in the attachment.
3. Testing is performed at least annually and whenever there is a change to the system that could affect the autoverification logic.
4. Autoverification assures that applicable QC samples have been run within the appropriate time period, with acceptable results. The LIS automatically checks quality control status prior to autoverification. Unacceptable QC status automatically disables the autoverification of patient results.
5. Parameters are selected for results comparison prior to auto release (autoverfication) of patient results. Parameters that will cause a manual review (auto disabling of autoverification) are listed as follows:

    a. LIS programmed Westgard QC rules that are violated or QC timing is exceeded.
    b. Delta checks are not passed. Patient results will not be auto released if the delta check function fails the set parameters and the result is considered a delta check sample. Delta checking will be performed on both autoverified and manually entered results.
    c. Patient results that fall within the established critical value parameters are not auto released.
    d. Instrument error flags or warnings that indicated potentially false patient result values are not auto released.
    e. Any instrument flag that is not specifically recognized by the autoverification program is not auto released.

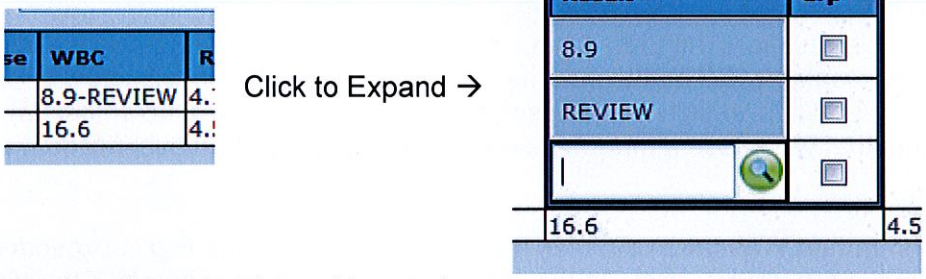
6. Laboratory staff members are able to manually suspend and re-enable autoverification in the event of a problem with a test method, analytic instrument or the autoverification program.
Refer to Section C.

7. Administrative director, supervisors and full time lead technologists in the core laboratory have the ability to re-enable autoverification that has been ***automatically disabled*** according to the quality control parameters in step 5.
8. Technical staff must troubleshoot the instrument, assure quality control is within range after troubleshooting and prior to notifying the administrative director, supervisor, or full time lead technologist to re-enable autoverification that was automatically disabled.
9. An audit trail is provided for all results autoverified.

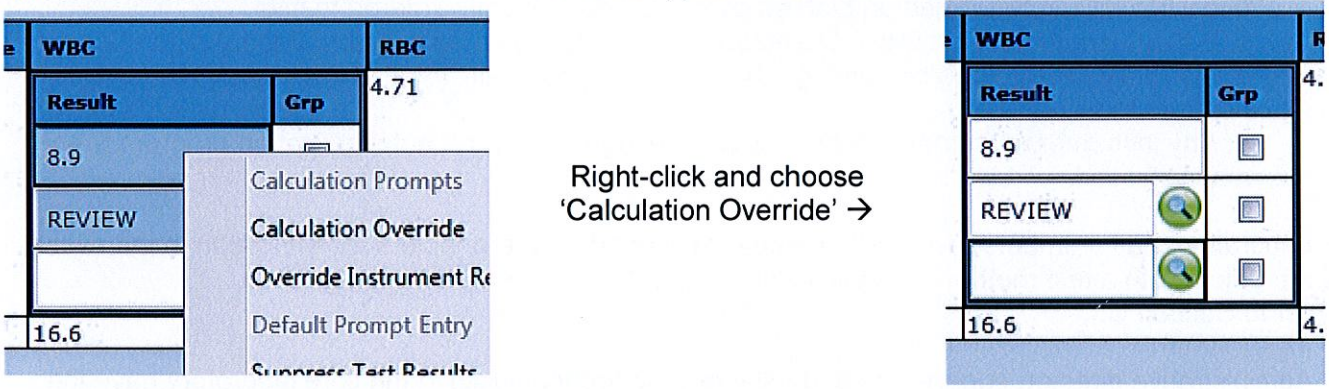
B. Results that Require Manual Accepting (Not Autoverified) in the Sunquest System This step must be performed AFTER each batch is run (even if the batch size is one specimen)

1. From the ***Result entry*** menu, in the configuration menu, select instrument.
2. From the Configuration window, select the appropriate configuration.
3. Select the ***Result*** button.
4. Select the ***Hide Empty Rows*** button. The results that have not been accepted will show on the screen.
5. Individual results that are critical will be colored red, and delta failures will be colored dark blue.
6. Once a cup is selected by clicking on it, important messages pertaining to the specimen can be viewed at the top of the screen in the 'Specimen Messages' area.
7. Where necessary you can edit a result or add, modify or remove comments by clicking on the result or its comments.

a. First, click on the result to expand it into separate boxes if it is not expanded already.



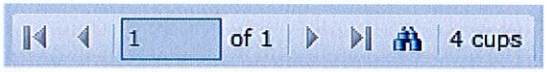
b. If the result and comments are blue and you cannot edit the result, right-click on it and choose 'Calculation Override' from the menu that appears. You will then be able to edit the result.



b. Then, click on the section you wish to modify. Results and comments can be modified using the backspace and delete keys on the keyboard. Enter a single comment code on the blank line below the last existing comment. Place a semicolon (;) before any freetext. To add additional comment codes or freetext, press tab to another line.

8. If the instrument has flagged a result for review, the comment 'REVIEW' will be appended in the box under the result. If you plan to release this result, delete the 'REVIEW' comment by clicking on the result, then clicking on the box with 'REVIEW', and deleting it using the backspace key

If blue, right-click then choose 'Calculation Override
9. To view previous results for a patient, click the **Display Prev** button on the right side of the screen. A new window will open with the patient's old results. After reviewing the previous results, close the window to return to the resulting screen.
10. To finalize (accept) the result, click on the ***Release*** checkbox on the line for that sample's analyte results, then click the ***Save*** button at the bottom of the screen. Clicking Save finalizes any results that have been checked off for release.
11. After clicking ***Save***, a confirmation window will appear. Review the results on the screen then click ***Accept*** to file them.
12. After saving, any differential results will appear in a pop-up window, one patient at a time. Review the results and modify comments as necessary (see steps 5 and 6). Click Save to finalize.
13. After saving, the next differential will appear. Repeat step 11 until no more differential results appear.
14. Keep this screen open and frequently review it to assure all results have been finalized (accepted).
15. If there are a large number of unfiled cups, the results will appear on multiple pages. You can move between pages to review the different results by using the arrow buttons at the bottom left corner.

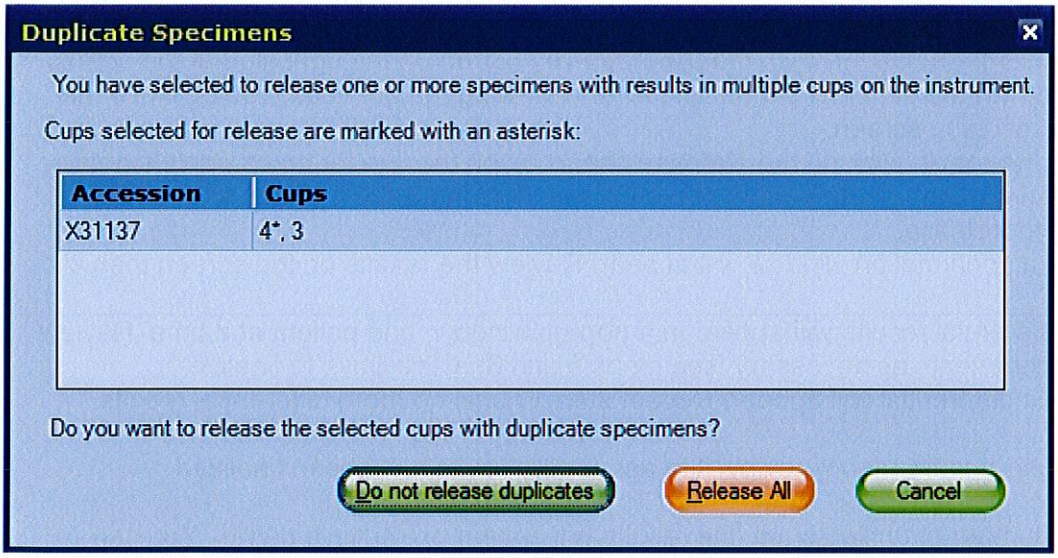


You must check this area to see if there is more than one page with results.

C. Reviewing and Accepting Quality Control (QC) Results for Instruments on Autoverification
All QC results must be manually reviewed.

1. Open Result Entry and open the instrument you want to accept QC results for.
2. Double-click the control code (e.g. C-A1C1). The individual resulting window will appear, and QC statistical information will appear, including mean, s.d. and any QC rules that have been violated.
3. Review the QC statistics. If the controls are acceptable, click the **Save** button to file them.

D. Duplicate cups
If there are multiple cups with results for the same tests on the same accession number, when you attempt to save the 'Duplicate Specimens' message will appear.
2. Double-check the accession number in Laboratory Inquiry to ensure that results are not already filed.
3. If results are not filed, return to Result Entry and click 'Release All' in the 'Duplicate Specimens' window, then close and reopen the Result Entry window.
4. If results are already filed on the accession number, close the result entry window and reopen it.



E. File Cleanup (OFC)

Cups that are not accepted will continue to appear in Result Entry as grayed-out rows. These should be cleaned up when there are 10 or more.

1. Check the analyzers, Result Entry screen and pending longs to make sure all results are filed.
2. Launch the text-based Sunquest system (SmarTerm) and enter function OFC.
3. Enter the method code, the press 'Enter'. Respond with 'Y' to any prompts, and press 'Enter' at the prompts for 'Start at/Stop with Cup Number'.
4. Close and reopen the Result Entry window.

F. Notes on crediting

After crediting any results that are in the Result Entry window and have not been filed (for example if the specimen is clotted), you must close and reopen the Result Entry window for the result to be removed from the list.

G. Manually enabling and disabling autoverification.

This step can be performed by the technical staff however this step will not override the automatic disabling of autoverification by Sunquest due to failed controls.

1. Log in to the text-based Sunquest system.
2. Enter function AUTF.
3. Enter the method code for the instrument for which you want to enable or disable auto-filing.
4. Read the prompt and respond with 'Y' = yes or 'N' =NO to enable or disable function from prior state.
5. Enter 'A' to accept.
6. You will be returned to the 'Method Code' prompt. Press 'Enter' to exit.
7. Enter 'Y' at the following prompt: 'Changes are to take immediate effect?'
8. The results processor will restart. Once complete, press 'Enter' to finish.

Reference:

Sunquest Information Systems Inc.: Ch. 18, *Laboratory for Windows User's Guide* for Sunquest Laboratory, 2013

Sunquest Information Systems Inc.: Ch. 10, *Instrument Interface Administrator's Guide* for Sunquest Laboratory, 2014

WRITTEN	APPROVED	
BY	BY	DATE
Terrence Newton LIS Manager	Philip Xiao, M.D., Medical Director	Established 2/17/2015 Revised 7/29/2015 Revised 9/30/15

DATE	REVIEWED BY	MEDICAL DIRECTOR REVIEW	DATE
7/2016	PXS		

REMOVAL		
BY	POSITION	DATE

CHANGE HISTORY

VERSION # 2	IMPLEMENTED ON: 3/18/2015		
Revised to reflect LIS programmed QC rules and who has the authority to re-enable autoverification and add section on finalizing results that did not get autoverified.			
PREPARED		APPROVED	
BY	DATE	BY	DATE

VERSION # 3		IMPLEMENTED ON: 7/8/2015	
Revised to include acceptance of differential results, instructions on removal of result flag comments, changing pages, viewing previous patient results, colors for critical and delta failures.			
PREPARED		APPROVED	
BY	DATE	BY	DATE
VERSION # 4		**IMPLEMENTED ON: 9/30/2015**	
Added a section with instructions for manually reviewing and accepting QC results.			
PREPARED		APPROVED	
BY	DATE	BY	DATE