Sutter Health
Sutter Roseville Medical Center

Origination:	*N/A*
Effective:	*N/A*
Final Approved:	*N/A*
Last Revised:	*N/A*
Next Review:	*N/A*
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Policy Area:	*Lab - Coag*
References:	
Applicability:	*Sutter Roseville Medical Center*

VerifyNow System Quality Control and Maintenance

Purpose

This document details procedures for maintenance and quality control of the VerifyNow System to ensure accurate patient results.

Policy

- Quality Control and Maintenance on the VerifyNow system will be performed at the scheduled time as described in the procedure
- The VerifyNow analyzers will remain powered on unless instructed by IL technical support or by the Supervisor for troubleshooting and/or maintenance purposes

Supplies and Equipment

- VerifyNow System analyzer
- VerifyNow EQC device
- VerifyNow Assay WQC
- VerifyNow PRUTest and Aspirin test devices
- VerifyNow System Preventative Maintenance Kit

Start up procedure

Step	Action
1.	Place the instrument in a location that allows adequate access to the power switch and power cord
2.	Locate the power switch on the back panel of the instrument.
3.	Power on the instrument by pushing the power switch to the "I" mark (designates on).
4.	When instrument is powered on then a series of internal diagnostics occurs and the green LED indicator on the lower left corner of the keypad remains illuminated.
5.	After the self testing is complete, the Start screen will display.
6.	Press the Next key to advance to the Main menu.

7.	Allow the instrument to warm up for at least 15 minutes prior to use. Note: A flashing message will display while the instrument is warming up. User will not be able to advance to the next step until after warm up message no longer displays.
8.	From the Main menu, enter the operator ID and password to perform QC and patient testing.

Shutdown procedure

Step	Action
1.	Prior to shutting down the instrument, ensure that all operations involving the VerifyNow instrument are complete
2.	Locate the power switch on the back panel of the instrument.
3.	Power off the instrument by pushing the power switch to the "O" mark (designates off).

Quality Control Frequency

In addition to internal quality checks that are performed on every testing cycle, Electronic Quality Control (EQC) and Wet Quality Control (WQC) must be performed at regular intervals

QC Type	Frequency
EQC	• Daily on shift 1 • Every 8 hours of patient testing on shift 2 and shift 3 • As needed for troubleshooting • After resetting the date and time
WQC	• Monthly • Every new lot or shipment of testing devices • If records indicate temperatures are outside of acceptable reagent storage range • As needed for troubleshooting

EQC Procedure

EQC will be performed daily and every 8 hours of patient testing. The VerifyNow System will not allow patient testing if EQC has not been successfully performed.

Step	Action
1.	If not already powered on, turn the analyzer on. The system should warm up for 15 minutes prior to use.
2.	From the Main menu, enter your operator ID and password. Note: Scan your ID badge barcode for your operator ID and password is 123
3.	From the main menu, press the key next to the QC icon.
4.	When the image of the QC device is displayed, remove the EQC device from the storage area. Hold the testing device by the finger grip.
5.	Insert EQC device into test port until it clicks. The analyzer will beep twice. Close test port cover.
6.	The instrument will automatically proceed with the EQC test. A countdown screen will display while the EQC is running. When EQC is complete, the screen will display a prompt to remove

	the EQC device.
7.	Open port cover, remove EQC device, and return device to the storage bay. Note: When not in use, the EQC device is kept in the storage bay. If EQC device is lost or damaged, the instrument will be imoperable
8.	After the EQC device is removed from the port, the instrument will beep and a calculation screen will display prior to generating the final result.
9.	Document performance of EQC on the VerifyNow instrument maintenance log. Press key next to printer icon to print results.
10.	If EQC passes, continue to patient testing.
11.	If EQC fails, identify the failed parameter. It will be indicated with an arrow to the right of the measured parameter. Press the next key and perform any described corrective action.
12.	Once corrective action is completed, repeat EQC. Document corrective action and repeat results on EQC log. Print results if printer is available.
13.	If repeat EQC passes, continue to patient testing.
14.	If repeat EQC fails, contact Technical Support and notify the Supervisor. Do not use VerifyNow system for patient testing until resolved.

WQC Procedure

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1.</td><td>Prepare Controls
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Level 1</td><td>Ready to use diluent. No preparation required</td></tr>
<tr><td>Level 2</td><td>• Inspect pellet. It should appear pink. If it appears red, smaller than usual, or stuck to vial, discard and use a new pellet
• Remove cap from vial with the pellet. Remove cap from the diluent tube by twisting and pulling the cap simultaneously
• Pour the pellet into the diluent vial and mix 4-5 times
• Control material should be used within 15 minutes of reconstitution</td></tr>
</table></td></tr>
<tr><td>2.</td><td>If not already powered on, turn the analyzer on. The system should warm up for 15 minutes prior to use.</td></tr>
<tr><td>3.</td><td>From the Main menu, enter your operator ID and password.
Note: Scan your ID badge barcode for your operator ID and password is 123</td></tr>
<tr><td>4.</td><td>From the main menu, press the press the key next to the QC icon.</td></tr>
<tr><td>5.</td><td>When the image of the QC device is displayed, remove the test device from the foil pouch just before use. Handle it by the finger grip.</td></tr>
<tr><td>6.</td><td>When prompted by the instrument:
• Remove the needle sheath by pulling directly up on the sheath. Do not twist the sheath as this may remove the needle
• Open the sample compartment cover</td></tr>
</table>

	• Insert the device into the instrument device. Press down until it clicks into place.
	If / **Then** The test device is the first from a new lot number of test cartridges → • When barcode screen is displayed, using the barcode scanner, scan the barcode on the bottom of the test device until an audible beep is heard which indicates that the information was read • Proceed to step 7 when test device pouch barcode is read If test device is from the current lot of test cartridges → Proceed to step 7
7.	Mix the level 1 diluent QC tube by inversion 5 times before use.
8.	Wait for the image of the tube to display then insert the QC tube into the testing device with rubber stopper facing down.
9.	Close the sample compartment cover. The instrument automatically draws the sample from the collection tube and proceeds with analysis. DO NOT attempt to remove the QC tube while the test is in progress. A calculator will display when the test is near completion.
10.	When the assay is completed, the result will be displayed.
11.	Record WQC results on the VerifyNow system WQC log. Press key next to printer icon to print results.
12.	Open the instrument cover, remove the testing device and QC tube together and dispose of in the Sharps container. Close the sample compartment cover.
13.	Record acceptable QC ranges from the testing device packaging on the VerifyNow system WQC log. Compare the QC result to the acceptable range.
	If / **Then** WQC passes → • continue to next level of QC step 14 WQC fails → • perform EQC to validate instrument is working properly • if EQC passes then prepare new WQC level 1 and repeat on the analyzer with new test device • if EQC fails then refer to the EQC procedure steps 11-14 • Do not use the VerifyNow system until problem is resolved
14.	Press the Next key to return to the Main Menu.
15.	Retrieve another test device
16.	Repeat steps 4-14 using the prepared level 2 WQC

Calibration

All test devices are calibrated at the factory and do not require user calibration. However, calibration information for each new lot of reagents must be scanned into the VerifyNow system. The information only needs to be scanned once per lot.

Step	Action
1.	The instrument will display a barcode prompt when a new lot of testing devices is detected.
2.	Place test device pouch so that it aligns with the barcode reader on the left side of the analyzer.
3.	An audible beep will be heard when the analyzer receives the information.
4.	Refer to Quality Control section for actions required for new reagent lots.

Maintenance Schedule

Maintenance will be performed according to the schedule:

Action	Frequency
Run EQC	Daily and every 8 hrs of patient run
Use Cleaning Device	Bi-weekly (every other week)
Clean fan filter	Bi-weekly (every other week)
Clean exterior surfaces	Monthly
Replace fan filter	Annually

Maintenance

Refer to the “Cleaning and Maintenance” section of the Verify Now System User Manual for additional information

- Maintenance actions may be performed more frequently if indicated by troubleshooting guide or technical support
- Use of the cleaning device more than once a week is not recommended since excessive cleaning can damage the instrument
- Instrument power must be off before cleaning or replacing fan filter
- The fan filter may be cleaned by either vacuuming or rinsing the filter with water and drying thoroughly

Cleaning Device Procedure

Follow the instructions to use the Cleaning Device on the VerifyNow System

Step	Action
1.	Remove the Cleaning Device from the pouch.
2.	Grasp the handle and **remove the opaque tape strip. Discard strip**.
3.	Open the sample compartment cover and insert the Cleaning Device into the instrument until it clicks into place. Note: The instrument does not need to be in any particular mode to use the Cleaning Device.
4.	Leave the device in the test port for 5-10 seconds. **Note: Do not leave device in place for longer than 10 seconds. The instrument may be damaged.**
5.	Remove the Cleaning Device, close the sample compartment cover, and discard Cleaning Device. The Cleaning Device is for single use only.

6.	Repeat with a second Cleaning Device if there is visible dust and debris on the first cleaning device.

Supporting Documents

- Form A: VerifyNow System Wet Quality Control Log
- Form B: VerifyNow System Maintenance Log

Related Procedures

- Performing the VerifyNow Aspirin Test
- Performing the VerifyNow PRUTest

References

- VerifyNow System Operating Manual
- VerifyNow Aspirin Package Insert
- VerifyNow PRUTest Package Insert
- VerifyNow WQC Package Insert
- VerifyNow Cleaning Device package Insert

All revision dates:

Attachments

Form B: VerifyNow system maintenance log
Form A: VerifyNow system Wet control log