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VerifyNow Operational Procedure

Introduction and Principle

The VerifyNow® System detects platelet activity by measuring in vitro platelet aggregation in a blood sample exposed to specific agonists. This includes inhibition of platelet activity in response to common antiplatelet therapies. The VerifyNow® System is a whole blood which measures platelet-induced aggregation as an increase in light transmittance. It consists of a turbidimetric-based optical detection instrument, single-use test devices, and associated quality controls.

There are two types of VerifyNow® tests: The Aspirin Test and the PRUTest. Each test device contains a lyophilized preparation of human fibrinogen coated beads and a platelet agonist. The platelet agonist varies by test type. Each test is based upon the ability of GP IIb/IIIa receptors on activated platelets to bind to fibrinogen-coated beads. When the activated platelets are exposed to the fibrinogen-coated beads, aggregation occurs in proportion to the number of available platelet receptors. The instrument is designed to measure this aggregation as an increase in light transmittance.

This procedure provides instructional guide for the basic operations, maintenance, and quality control.

Scope

This procedure is intended for Clinical Lab Scientists (CLS) and Medical Lab Technician (MLT) trained in handling the analyzer.

Policy

- Daily, biweekly, monthly, and annual maintenance must be done and documented
- Electronic Quality Control (EQC) must be run each day of use prior to instrument use to monitor the performance of the analyzer during which the software will verify instrument optics performance, reagent mixing and instrument pneumatic. It also confirms correct calibration parameters and simulates testing at two levels of results to check correct acquisition and calculations
- Unless IQCP is established by the performing lab, both levels of Wet Quality Control (WQC) must be performed every run, new lot and new shipment of test device kits, or at minimum every 30 days.
- Level 2 of Wet Quality Control (WQC) should also be run when a problem is suspected with the VerifyNow® System
- Follow local IQCP if already established.

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Specimen sources

Whole blood collected in Greiner light blue top tubes containing 3.2% Sodium Citrate. (Ref# 454322)
NOTE: The use of sample collection tubes other than that listed may adversely affect test results.

Specimen collection

A. Peripheral Samples
- Patient preparation: None required
- Specimen Type: Whole blood samples must be collected in or immediately transferred to Greiner 2.0 ml partial fill blue top tubes containing 3.2% Sodium Citrate. The tube must be filled to its intended whole blood capacity (indicated by small black line).
- Instructions for Sample Collection by Venipuncture:
  1. Identify a site that is free of any peripheral venous infusions. Apply the tourniquet and identify the phlebotomy site.
  2. Release the tourniquet and cleanse the phlebotomy area.
  3. Reapply the tourniquet. It is important to minimize the amount of time that the tourniquet is applied prior to filling the tube in order to avoid activating the platelets while obtaining the sample.
  4. Draw a discard tube first (about 2 mL) using a regular blue top or red top. Continue the phlebotomy and obtain the appropriate volume of blood in the sample tube of at least 2 ml of whole blood. Draw <u>at least 2</u> Greiner tubes, each filled to its intended capacity (indicated by small black line). Collection should be performed with care to avoid hemolysis or contamination by tissue fluids.
  5. Do not draw a sample for any platelet function test after a tube that contains EDTA (purple top). Always draw the tube(s) for the VerifyNow® Test first.
  6. Gently invert the citrated tube containing whole blood 5 times immediately after collection to mix the blood with the anticoagulant and prevent clotting.

B. Indwelling Catheter
- Discard the first 5 mL from an indwelling catheter to clear the line. Ensure the catheter is free of clots.
- Immediately transfer blood to a 2 mL Greiner blue top citrated vacuette tube and fill to the black line (half-tube). Do not under-fill. If drawing blood for a CBC at the same time, fill the CBC tube last.
- Gently invert the tube at least 5 times to ensure complete mixing. Do not shake. Samples with evidence of clotting should not be used.
- Label tube with properly with patient medical record number, name, date and time of collection. Do not refrigerate. Do not put in pneumatic tube system.

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Specimen transport

- Transport immediately to the Laboratory.
- Sample must be transported by a laboratory assistant or nursing department/unit staff to the laboratory avoiding shaking or agitation during transport.
- Do not transport the samples using the pneumatic tube system otherwise the sample will be rejected because of sample integrity.
- Do not refrigerate, freeze, or centrifuge the specimen.

Specimen storage and rejection

- See specific test requested on stability and storage.

Equipment

- Werfen VerifyNow® Analyzer

Quality Control Reagent

The following contains the list of reagents and/or media required.

Description	Vendor	Storage
VerifyNow® Assay WQC (REF 85047)	Werfen	Room Temperature (15°C to 25°C)

Materials and supplies

The following contains the list of materials and supplies required.

- Electronic QC Device
- Greiner Bio-One Vacuette® 2ml blood collection tubes containing 3.2% sodium citrate. (REF # 454322)

Safety

Refer to the safety manual for general safety requirements.

Before you begin

The VerifyNow® analyzer should be left on, if turned off, power on the instrument using the power switch at the back panel. The instrument will power on and perform a self-testing routine lasting approximately 30 seconds. After the self-testing is complete, the Start screen will display. Press the Next key to advance to the Main Menu. The instrument should be allowed to warm-up for at least 15 minutes prior to use. A flashing message will display while the instrument is initially warming up. During this time the icon keys are inactive. Warm up message no longer displays when it's ready.

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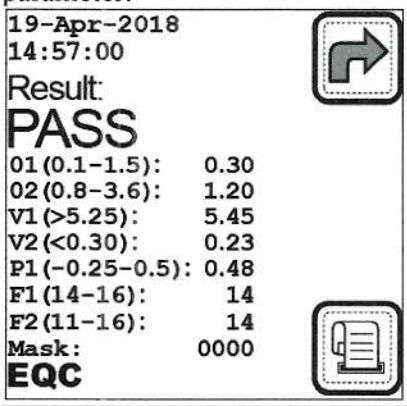
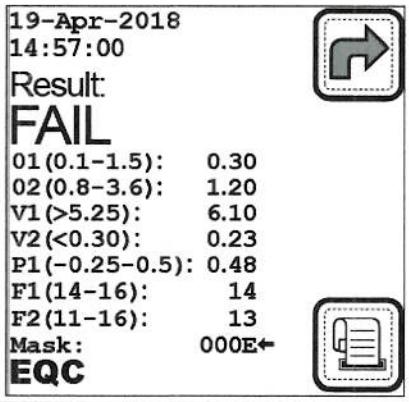
Quality Control Procedure

Follow the steps below to perform quality control.

A. Procedure to perform EQC

Electronic Quality Control (EQC) is the primary quality control mechanism for the VerifyNow® Instrument.

- It consists of a reusable device that is inserted by the operator into the test port and is used to perform a comprehensive testing routine that confirms performance of key instrument components.

Step	Action
1	If required, enter Operator ID and Password.
2	The EQC Device is located in a storage port on the right side of the instrument. 
3	Choose QC by pressing the QC button from the main screen. 
4	Open instrument cover. Remove the EQC Device from the storage port, open instrument cover and insert the EQC Device into the instrument. Close instrument cover. 
5	EQC will automatically run. A countdown screen will display while EQC is in progress. When the EQC is complete, the instrument will prompt the user to completely remove the device from the test port.
6	Open instrument cover and remove the EQC Device and return it to the storage port. Close instrument cover. A result of PASS or FAIL will be displayed. In addition, numeric values will be reported for the diagnostics, along with acceptable range and parameter.  
7	If the EQC Device result is "FAIL", repeat the EQC. If the result is "PASS", continue with patient testing. If the EQC result is

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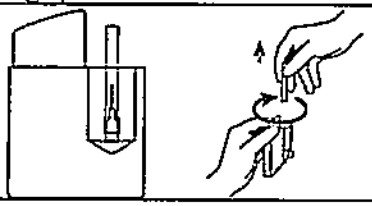
	"FAIL" after the second analysis, use the cleaning cartridge as described in the Maintenance Section below and rerun the EQC.
8	Print result  or return to the Main Screen 
9	Document all EQC result.

B. Procedure to perform WQC

The VerifyNow® instrument also supports two levels of wet quality controls.

Wet Quality Control (WQC) is intended to be used with a diluent and a test device as a basis for quantitative quality control. Specifically, the WQC measures two levels of turbidimetric signal that verify the dynamic range of the instrument.

One of these signals is at the level that would be observed in a patient with a minimal amount of platelet aggregation (negative control), and the other represents a patient who demonstrates a significant amount of aggregation (positive control).

1	If required. enter Operator ID and Password.
2	Press the QC Icon key  . The *Insert Cartridge* screen will display.
3	Open the foil pouch and remove the test device. The test device should only be handled by the finger grip.
4	Remove the protective sheath from the test device needle by pulling directly up on the sheath. Do not twist the sheath as this may remove the needle. 
5	Open instrument cover. Insert the test device at the instrument prompt. If this is a new device lot, the Bar Code prompt will display. At prompt, place the test device pouch approximately one inch in front of the barcode reader found on the left side of the instrument, so that the light shines on the center of the barcode. An audible beep will signal that the instrument has read the bar code, and the testing will continue.

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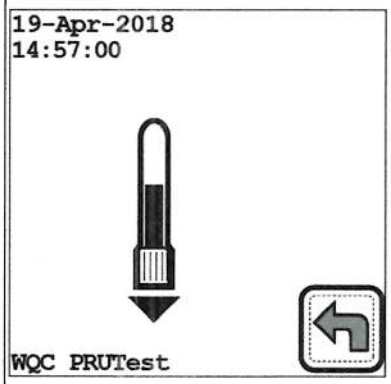
6	Prepare the WQC Sample. • Level 1: Test Control Level 1 is ready for use as provided • Level 2: Remove the stopper from the tube containing the Level 2 Control diluent by twisting and pulling the cap simultaneously. Add the Level 2 control pellet to the level 2 control diluent and replace the stopper by pressing and turning simultaneously. Invert the tube gently 5 times to mix]
7	At the prompt, insert the sample onto the device needle. Close instrument cover. The test will automatically begin.   **CAUTION**: The sample is under pressure once it is inserted onto the device needle. DO NOT REMOVE the test device or control tube from the instrument until the test is completed.
8	The instrument will run the test and display the result.
9	Print or record the result and return to the Main Screen.

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10	Open instrument cover. Remove the test device by grasping the device finger grip and pulling straight up. Do not remove the sample or diluent tube from the device. Close instrument cover. 
11	Discard the used device and quality control tube as biohazardous waste.
12	The instrument is ready to test the next sample.
13	Determine that the WQC result is within the acceptable range of values printed on the test device pouch provided with the test. • If the WQC is in control, proceed with the testing of patient samples. • If the WQC result does not fall within the stated range, perform an EQC test to ensure that the equipment is working properly. If the EQC is OK, prepare a new WQC sample and repeat the WQC procedure with a new test device. • If the WQC result fails on the second attempt, contact VerifyNow Technical Support. **Do not test patients until QC failure is resolved.**
14	Document all WQC results. • **NOTE:** VerifyNow P2Y12 and Aspirin test devices are calibrated by the manufacturer at the factory. This calibration information is contained in the barcode on the pouch of each test device. • The barcode must be scanned whenever a new lot of test devices is to be tested. After that no additional calibration is performed by the user, • Calibration verification is performed by the use of wet Quality Control materials with every new lot of reagent and at specified time intervals. Tests of platelet function are non-linear, and no additional calibration verification is required.

Recall of EQC or WQC Results:

The last 100 EQC and WQC results can be recalled at any time. To recall:

1. Press the Maintenance button from the Main Screen.
2. Press the Next arrow 3 times to advance to the Maintenance Submenu where folders are displayed with the words EQC (2nd button) and WQC (3rd button).
3. Press the appropriate button to recall the EQC or WQC results.
4. **Press the back arrow to return to the Main Screen.**

Maintenance

The following activities comprise the preventative maintenance for VerifyNow. Document all maintenance performed in the Maintenance Chart.

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A. Daily Maintenance
- Perform Electronic Quality Control (EQC)

B. Biweekly Maintenance
- Use the cleaning Device

C. Monthly Maintenance
- Clean exterior surfaces

D. Annual Maintenance
- Replace the fan filter

Maintenance

Daily Maintenance

1. Run Electronic Quality Control (EQC) as described above.

Biweekly Maintenance

Depending on the room conditions, small amounts of dust and debris may build up on the pneumatic port connection of the instrument. A single use, disposable cleaning device is provided to remove this debris. It consists of a clear plastic component with an adhesive strip. Use the cleaning device to remove debris from a pneumatic port connection inside the test device port according to the following procedure.

Step	Action
1	Locate the cleaning device pack.
2	Grasp the cleaning device using the finger grip and **remove the clear plastic tape.** Discard the tape.
3	Open the cover and insert the cleaning device into the test device port until it clicks. The adhesive strip removes dust and debris on the internal pneumatic port cleaning strip. **NOTE:** The instrument does not need to be in any particular mode to use the cleaning device.
4	Leave the cleaning device in the test port for five seconds, but never longer than ten seconds. **CAUTION:** Leaving the cleaning device in the test port for an extended period of time can damage the instrument from adhesive adhering to the internal pneumatic port.
5	Remove the cleaning device completely from the test device port. Discard the device. The cleaning device is for single use only.
6	Repeat using another cleaning device if, upon inspection, there is visible dust and debris.

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Monthly Maintenance

Occasionally, a liquid may spill near the instrument, or small amounts of dust may build up on the exterior of the instrument. Periodic cleaning of the exterior surface may be performed to remove accumulation on the instrument.

Step	Action
1	Cleaning solutions may be applied by moistening a soft, lint-free cloth, and/or a cotton swab. Do not allow liquids to flow freely or be sprayed on the instrument
2	**NOTE:** Use the recommended cleaning solution on the exterior surfaces.
3	After cleaning with one of the solutions, a cloth moistened with fresh water should be used to dilute and remove all of the residual cleaning solution from the instrument's surfaces.
4	Wipe the EQC device with a damp cloth moistened with isopropyl alcohol.

Annual Maintenance

The instrument is equipped with an exterior fan vent to cool the internal electronic components. Depending on the room conditions, small amounts of dust and debris may accumulate over time within the fan filter and obstruct airflow. Periodic cleaning of the fan filter may be performed to avoid overheating of the instrument.

Step	Action
1	Power off the instrument ("O" designates off).
2	The fan filter is held in place by a press fit retainer. Using your fingernail or a small tool, gently pull from the center of the filter retainer. **NOTE:** There are no screws to be removed.
3	Remove the fan filter and inspect it for dust accumulation.
4	If necessary, replace it with a new filter.
5	Gently replace the fan filter and plastic filter retainer. Do not position the instrument so that airflow to the fan is obstructed.

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Limitations

The following should be considered for test limitations.

1. To minimize problems during specimen handling, test performance and reporting of test results, the area where testing is performed must contain the proper workbench space, ventilation, utilities, and supplies necessary for conducting the type and volume of testing performed.
2. Place the VerifyNow® instrument on a clean, firm, level bench top, which is free of excessive vibration from equipment such as a centrifuge. Provide adequate space around the instrument to access instrument components and be sure the area is free from exposure to unusual temperature fluctuations.
3. Do not locate the VerifyNow® instrument in an area next to a source of heat, air conditioning or in direct sunlight. Do not place the instrument under an incandescent light source.
4. The VerifyNow® instrument operates at ambient temperature (18-32°C or 64-90°F) and up to 85% humidity without condensation.
5. The lyophilized agent is hygroscopic and can degrade after prolonged exposure to room air. Therefore, the test device should be used shortly after removal from the foil pouch.
6. Store reagents and quality control material according to the package directions. The test devices can be stored either at room temperature or in the refrigerator.
7. Delays in testing or difficulty of specimen collection may result in spurious values. Do not test any sample that is clotted, too old, hemolyzed, or that has been mishandled or mislabeled.
8. When results are not within the expected limits, the possibility of improper sample collection or handling should be investigated. Repeat the test using a new test device and sample.

Back-up and Re-installation after Equipment Repair

- Care and attention should be taken in referring samples to the closest performing laboratory in the event that the local VerifyNow analyzer is malfunctioning, keeping in mind specimen stability window.
- Before a loaner VerifyNow analyzer can be used for patient testing, verification studies must be made consisting of accuracy and precision.
- When a VerifyNow analyzer is coming from vendor repair, functional verification should be performed. This may consist of a EQC, a positive wet control, a negative wet control, and two split samples correlation with another validated analyzer.

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Non-Controlled Documents

The following non-controlled documents support this policy.

Werfen. 2018. VerifyNow Assay Wet Quality Control (WQC), Package Insert, English, VN1018NEU 01, San Diego, CA.

Werfen. 2022. VerifyNow Operator Manual, 000VN5006EN.C 02, English, 04/2022. San Diego, CA.

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Signature Manifest

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Coagulation Regional Docs

Operations Director Approval

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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	28 Aug 2024, 02:13:33 PM	Approved