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Kaiser Permanente Medical Care Program California Division - South	SCPMG Laboratory Systems Coagulation Procedure

VerifyNow® Aspirin Test™ Procedure for Platelet Aggregation

Purpose or Principle or Introduction

The VerifyNow Aspirin Test is a qualitative test to aid in the detection of platelet dysfunction due to aspirin ingestion. The test is not for use in patients with underlying congenital platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents (may be used in patients treated with selective COX-2 inhibitors, e.g., celecoxib (Celebrex®).

Aspirin affects platelet function by irreversibly inhibiting the cyclooxygenase-1 (COX-1) enzyme involved in the conversion of arachidonic acid to thromboxane A2, which ultimately activates the GPIIb/IIIa receptors involved in platelet aggregation. If aspirin has produced the expected anti-platelet effect, such aggregation will not occur. The VerifyNow Aspirin Test incorporates the agonist arachidonic acid to activate platelets. The Aspirin Test is designed to measure platelet function based upon the ability of activated platelets to bind fibrinogen. Fibrinogen-coated microparticles aggregate in whole blood in proportion to the number of unblocked platelet GP IIb/IIIa receptors. Light transmittance increases as activated platelets bind and aggregate fibrinogen-coated beads. The instrument measures this change in optical signal caused by aggregation.

Scope

This procedure is intended for trained Clinical Laboratory Scientists (CLS) and Medical Laboratory Technicians (MLT) that will perform the waived VerifyNow Aspirin test.

Specimen collection and specifications

- Patient Preparation: Specimen should be collected between 2 and 30 hours after ingestion of aspirin.
- See VerifyNow Operational Procedure for general collection instructions.

Specimen transport

- Specimen must be hand carried to the laboratory and must not be sent via pneumatic tube system.

Specimen stability and storage

- The sample must be incubated at room temperature for 30 minutes prior to testing and can be used up to 4 hours after collection if stored at room temperature (18 to 25 °C). *Do not refrigerate or freeze specimen.*

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Specimen rejection

- Samples with evidence of clotting must not be used.

Instrument

VerifyNow analyzer

Reagent

The following are the reagents necessary to perform the assay.

- VerifyNow Aspirin Test device (reagent device), box of 25 test devices (PN 85053), OneLink item number 10338540. All required reagents are contained within the individually packaged ASP Test device.
  - Each individually sealed VerifyNow Aspirin test device contains the lot number and expiration date stamped on the foil pouch and contains lyophilized fibrinogen-coated beads, platelet agonist, peptide, bovine serum albumin, stabilizer, and buffer.
  - Store test devices at 2°C to 25°C (36° - 77°F). If refrigerated, allow test devices to reach room temperature, 18°C to 25°C (64° - 77°F) prior to use.
  - Test device should remain sealed in the foil pouch until ready for use to prevent damage by humidity.
  - Once removed from its foil pouch, the test device must be handled only by the finger grip and used immediately.
  - Do not use the VerifyNow Aspirin test device beyond the expiration date.

- VerifyNow Assay WQC Kit, Catalog #85047, OneLink item number Box of 6 Diluent Tubes and 6 Pellets.
  - Control materials should be stored at 15°C to 25°C (59° - 77°F).
  - Control material is suitable for use until the expiration date stamped on the label.
  - Test Control Level 1 is ready for use as provided.
  - Do not open the vial containing the Level 2 Control pellet until immediately prior to use.
  - Control material should be used within 15 minutes of reconstitution. Do not freeze.

Receipt of Shipment

When a shipment of kits is opened, check the temperature located on the outside of the box.

- If the temperature indicator is activated, the indicates exposure to elevated temperatures and a VerifyNow Level 2 WQC should be performed.
- If the Level 2 WQC result does not fall within the accepted range on the package insert, call Technical Support at (800)643-1640.

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Materials and supplies

The following contains the list of materials and supplies required.

- Electronic Quality Control (EQC).
- Greiner Bio-One Vacuette® partial fill blood collection tubes (2 mL fill volume) containing 3.2% sodium citrate. Greiner Catalog #454322 or Nipro catalog #NP-CW0185-1 blood collection tube (1.8 mL) containing 3.2% sodium citrate.
- Phlebotomy supplies, including needle of 21 gauge or larger.

Safety

Refer to the safety manual for general safety requirements.

Calibration and Calibration Verification

- VerifyNow 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. The system will not allow a test device to proceed without the lot number calibration information being scanned into the system. If a new lot of test devices is being used, the instrument will prompt the user by displaying a barcode icon after the test device is inserted.
    a) 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 reader.
    b) An audible beep will be heard when the instrument receives the required information.
    c) The user needs only to perform this action once per lot.
- 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 (refer to Quality Control Procedures below), with periodic review of QC results by the laboratory technical supervisor.

System (Internal) Quality Control for Each Sample Tested

- The VerifyNow Aspirin test contains internal controls.
- The instrument automatically verifies sample filling, correct fluid transfer, and mixing. It also monitors the electronic and mechanical components.

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- Each test device incorporates two levels of quality control to identify invalid test runs caused by random errors, reagent degradation, or inappropriate blood samples.
- Before platelet activation and fibrinogen binding begin, the negative internal control performs a test for non-specific aggregation. A failure of this test will result in an Attention message (attention 24) by the VerifyNow instrument, and no Aspirin Reaction Units (ARU) result will be reported.
- During the active phase of the test, the positive internal control channel monitors the reaction and calculates Control Units, which must fall within specified limits. A failure of the positive control may be indicative of reagent degradation or an abnormal sample. The VerifyNow instrument will report an Attention 24 or Attention 28 message, and no ARU will be reported.

Procedure

Follow the steps below to test patient specimen for Aspirin.
Refer to the VerifyNow Operational Procedure for comprehensive instructions on the analyzer.

Step	Action
1	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. This will initiate the following startup checks in preparation of the assay: a. A system program and data memory check to ensure memory integrity b. A system temperature check to ensure the test warming plate reaches and maintains the proper temperature. c. A system checks of proper operating voltages; and d. A system intra-communication validation.
2	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.
3	If sufficient time has elapsed, the instrument will prompt you to perform an EQC. Refer to VerifyNow Operational Procedure for steps in running EQC. The following checks are performed: a. Instrument optics.

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	b. Pneumatics system that draws the sample into the test device for reaction and measurement. c. Reagent mixing parameters and sample data acquisition. d. Correct calibration parameters. If required, enter User ID and Password After a **PASS** has been achieved on EQC, the instrument will be ready to perform an assay.
4	i. When the initial screen displays, press the Assay key. ii. Enter the patient ID and then press the Next key. The screen will prompt to insert the assay device. iii. Prepare materials needed – assay device and the sample tube. Do not remove the assay device from the foil pouch until ready to use.
6	Open the foil pouch and remove the test device just before use. Hold the assay device by the finger grip. Note: Each assay device has a finger grip. Avoid handling other surfaces of the assay device. • If WQC is indicated, perform and determine acceptability of WQC.
7	Remove the needle's protective sheath by twisting clockwise until resistance is met. While continuing to twist clockwise, pull on the sheath.
8	Open instrument cover. Insert the test device at the instrument prompt. • If this is a new test devices lot, the barcode 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 reader. An audible beep will signal that the instrument has read the bar code, and the testing will continue.
9	At the instrument prompt, invert the sample tube at least 5 times, Wait for the "Insert Tube" icon to display, then insert onto the needle in the test device. If your instrument has test port cover, close it now. CAUTION: Sample is under pressure. Do not remove sample tube from test device. Only remove the test device from the instrument after testing is completed.
10	The instrument will run the test and display the result in approximately 5 minutes.

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11	Open the cover. Remove the test device and tube together in one piece by grasping the test device finger grip and pulling straight up. Do not separate the tube from the test device. Close the cover.
12	Dispose of the entire test device/sample tube in appropriate biohazard waste container.
13	Record or print the sample result. The instrument is ready to test the next sample.

Diagnostic Error Display Messages

Under certain conditions, a test run may be aborted. In this case, the instrument will display an Error or Attention message. Please refer to the VerifyNow User Manual for a more detailed explanation of these messages.

1. In the case of an Attention 24, an EQC should be performed to test instrument function. If the QC passes, the VerifyNow system is functioning normally. In these cases, the problem may be associated with the blood sample and the following causes of Attention 24 should be investigated:
   - The patient being tested is on an interfering substance such as abciximab (ReoPro), eptifibatide (Integrilin) and tirofiban (Aggrastat).
   - An improper blood collection technique was used to draw the sample.
   - The discard tube was used to run the test.
   - The patient being tested has a low platelet count, a low hematocrit, or an inherited platelet disorder.
   - A Wet QC sample was run in Patient Test mode rather than QC mode.
   - If none of the above can be determined to be the cause of the Attention 24, the WQC Level 2 may be run to confirm the integrity of the test device and the reagents.
2. In the case of Attention 28, an EQC should be performed to test instrument function. If the EQC passes, the VerifyNow system is functioning normally. In these cases, the problem may be associated with the blood sample and the following causes for Attention 28 should be investigated:
   - The patient being tested has a Hematocrit outside the applicable range.

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Recalling Patient Results

In order to enable the recall of specific patient results, the instrument must be configured to require a Patient ID to be entered before each test is performed.

1. If required, enter User ID and Password.
2. Choose the second option (Button next to file folder) from the Main Screen.
3. Enter the Patient ID and press the arrow for Next.
4. An Aspirin test result is indicated by an "a".
5. Record or print the results. The most recent result is displayed, along with the date stamp indicating the date and time the test was performed. To toggle to other results, use the left and right arrow key.
6. If you choose the PRINT ALL icon, everything displayed below the blinking cursor will print.

Expected Values or Reference Range

Test results are reported as Aspirin Reaction Units (ARU), which are calculated as a function of the rate of aggregation.
Interpretation of results is based on the cutoff of less than or equal to 549 (<=549) ARU.

Interpretation / Results / Alert Values

For values that are...	Interpretation is that...
Greater than or equal to 550 ARU (≥550)	Platelet dysfunction consistent with aspirin has not been detected.
Less than 550 ARU (<550)	Platelet dysfunction consistent with aspirin has been detected.

- Results should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

Test Limitations and Method Notes

- 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.
- Place the VerifyNow Instrument on a clean, firm, level bench top, which is free of excessive vibration from equipment such as centrifuge. Provide adequate space around the instrument to access instrument components; be sure the area is free from exposure to unusual temperature fluctuations.

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- Do not locate the VerifyNow instrument in an area next to a source of heat, air conditioning or in direct sunlight.
- The VerifyNow Instrument operates at ambient temperature (18-32°C or 64-90°F) and up to 85% humidity without condensation.
- 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.
- Store reagents and quality control material according to the package directions. The Aspirin test devices can be stored either at room temperature or in the refrigerator.
- 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.
- When results are not with the expected limits, the possibility of improper sample collection or handling should be investigated. Repeat the test using a new test device and sample.
- Patients with inherited platelet disorders such as von Willebrand Factor Deficiency, Glanzmann Thrombasthenia and Bernard-Soulier Syndrome have not been studied with the VerifyNow Aspirin test.
- Patients receiving the following anti-platelet agents may not be tested with VerifyNow Aspirin test, based on documented interference testing results: GPIIb/IIIa inhibitors, dipyridamole, clopidogrel, non-steroidal anti-inflammatory drugs (NSAIDS) which inhibit COX-1 and/or COX-1, COX-2 enzymes (ibuprofen, naproxen, diclofenac, indomethacin, and piroxicam).
- The performance of VerifyNow Aspirin test on patients with acquired non-drug induced platelet abnormalities is not known.
- Patients who have been treated with Glycoprotein IIb/IIIa inhibitor drugs should not be tested until platelet function has recovered. This time period is approximately 14 days after discontinuation of drug administration for abciximab (ReoPro) and up to 48 hours for eptifibatide (Integrilin) and tirofiban (Aggrastat). The platelet function recovery time varies among individuals and is longer for patients with renal dysfunction.
- The VerifyNow Aspirin test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.

Controlled Documents

The following controlled documents support this procedure.

VerifyNow Operational Procedure

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Non-Controlled Documents

The following non-controlled documents support this policy.

Werfen. 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.

Werfen. 2018. VerifyNow Aspirin Test Device Package Insert, VN1011WEU 04, 05/18. San Diego,

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Signature Manifest

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Operations Director Approval

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