Document Title: VerifyNow P2Y12 Test
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Author	Effective Date	Supersedes Procedure #
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QC/QA	1		
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REVISION HISTORY

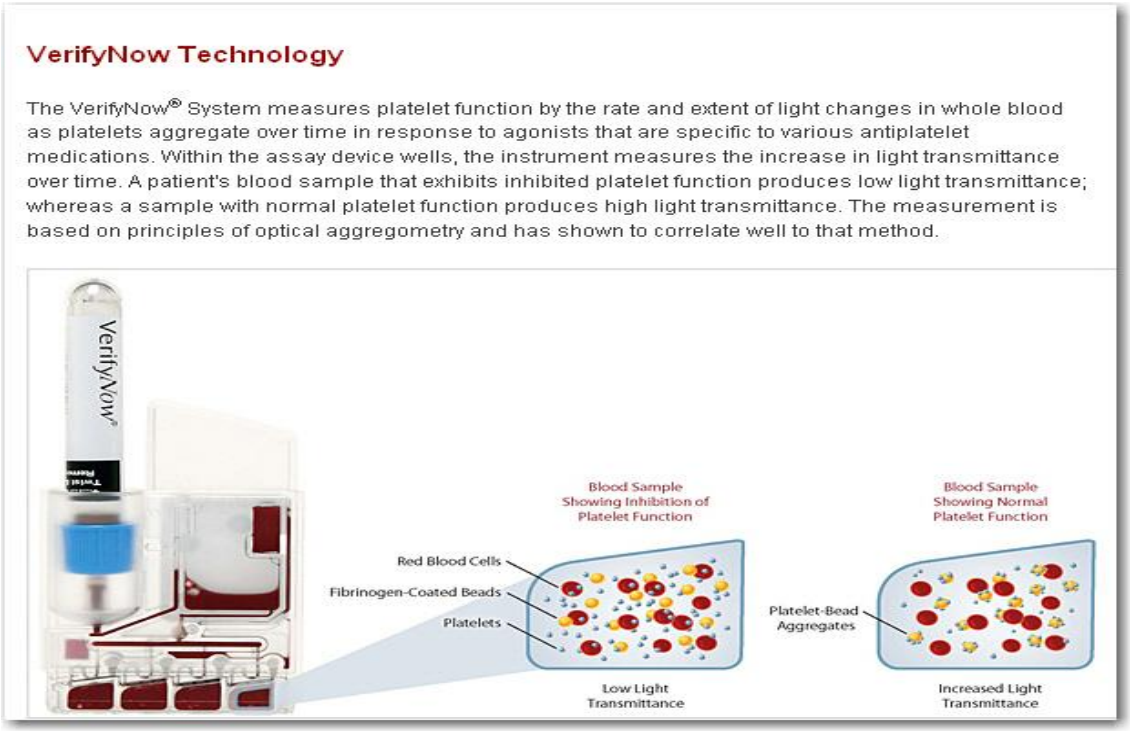
Procedure #	Revision Date	Reason for Revision
SH.CP.AU.hem.0057.0001	12/14/2009	NEW
SH.CP.AU.hem.0057.0002	1/14/2014	(see previous coversheet)
SH.CP.AU.hem.0057.0003	2/14/2018	Add section on running minimally every 30 days; add knowledge check

Title: VerifyNow (P2Y12) Test

I. PRINCIPLE

The VerifyNow® P2Y12 Test is designed to measure platelet P2Y12 receptor blockade. Substances known to specifically block the P2Y12 receptor include the thienopyridines class of drugs, including clopidogrel and prasugrel.

The test is based upon the ability of activated platelets to bind fibrinogen. Fibrinogen-coated microparticles aggregate in whole blood in proportion to the number of expressed platelet GP IIb/IIIa receptors. The rate of microbead aggregation is more rapid and reproducible if platelets are activated, therefore the reagents adenosine-5-diphosphate and prostaglandin E1 (ADP/PGE1) are incorporated into the assay channel to induce platelet activation without fibrin formation. The reagent is formulated to specifically measure P2Y12-mediated platelet aggregation. Light transmittance increases as activated platelets bind and aggregate with fibrinogen-coated beads. The instrument measures this change in optical signal and reports results in P2Y12 Reaction Units (PRU).
In a like manner, a second activator, iso-TRAP (Thrombin Receptor Activating Peptide) and fibrinogen-coated microparticles are incorporated into a second channel of the Test Device. Aggregation is induced via thrombin receptors; this estimates total possible platelet aggregation regardless of the presence of a P2Y12 receptor blocker. The instrument measures the change in transmittance in this channel, calculates the baseline platelet function for the sample, and reports the percent inhibition result for the sample.



II. PURPOSE

The VerifyNow P2Y12 Assay is a quantitative assay for monitoring and measuring an individual's response to the anti-platelet effects of P2Y12 inhibitors. This procedure provides the information to perform the VerifyNow P2Y12 assay to aid in the detection of platelet inhibition due to P2Y12 inhibitor therapy.

III. SCOPE

This procedure will be used by the UR Medicine Labs, Hematology-Chemistry Laboratory.

IV. RESPONSIBILITIES

Roles	Responsibilities
Quality	Ensure that procedure is followed when performing the VerifyNow P2Y12 assay.
Medical Director	Ensure that procedure is followed when performing the VerifyNow P2Y12 assay.
Management	Ensure that procedure is followed when performing the VerifyNow P2Y12 assay.
Employees	Follow procedure.

V. SPECIMENS

A. Patient Preparation: None required

B. 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).

C. Sample Collection by Venipuncture:

1. Identify a site that is free of any peripheral venous infusions.
2. Apply the tourniquet and identify the phlebotomy site.
3. Release the tourniquet and cleanse the phlebotomy area.
4. 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.

5. Perform the phlebotomy and obtain the appropriate volume of blood in the sample tube following a discard tube of at least 2 mL of whole blood. DO NOT DRAW A SAMPLE FOR ANY PLATELET FUNCTION ASSAY AFTER A TUBE THAT CONTAINS EDTA (PURPLE TOP). Always draw the sample 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.
7. Samples must be kept at room temperature. Do not refrigerate, freeze or centrifuge the samples to be used for the Verify*Now* Test.
8. Samples that are difficult to obtain may hemolyze or clot. Samples that are hemolyzed or clotted should be recollected.

D. Sample collection from Indwelling Catheters:

1. Ensure that the indwelling catheter is free of clots.
2. Obtain a discard of at least 5 mL. in order to clear the line.
3. Obtain the sample for testing with a second syringe.
4. Immediately transfer the blood to the appropriate collection tube.
5. Immediately gently invert the citrated tube containing whole blood at least 5 times to mix the blood with the anticoagulant and prevent clotting.
6. Samples must be kept at room temperature. Do not refrigerate, freeze, or centrifuge the samples to be used for the VerifyNow Test.
7. Samples that are difficult to obtain may hemolyze or clot. Samples that are or clotted should be recollected.

E. Sample Stability and Storage:

The sample must be incubated at room temperature for 10 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*.

F. Sample Precautions:

Collection of the blood specimen should be performed with care to avoid hemolysis or contamination by tissue fluids. Samples with evidence of clotting must not be used.

G. Handling Conditions:

The sample must be incubated for 10 minutes at room temperature prior to testing. If testing is delayed, the sample can be stored at room temperature (18 to 25 °C) for up to 4 hours. *Do not refrigerate or freeze specimen.*

VI. QUALITY CONTROL

A. Internal Quality Control

1. The instrument automatically verifies sample filling, correct fluid transfer and mixing.
2. The instrument monitors the electronic and mechanical components of the system.
3. The system verifies the expiration date of the assay device and prevents the operator from running a test on an expired device.
4. The system also detects certain operator errors, such as placing the assay device or the sample in the instrument at the wrong time, or removing the assay device before the test is complete. These internal checks prevent the reporting of inaccurate results.
5. Each assay 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. Failure of this test will result in an Error 24 by the Verify Now instrument and no PRU result will be reported. During the active phase of the test, the positive channel monitors the reaction and calculates Clinical Control Units (CU), which must fall within a specified range. Failure of this test may be indicative of reagent degradation or an abnormal sample. The instrument will report an Error 24 and no PRU result will be reported.
6. Each assay device contains an internal humidity sensor. When exposed to excessive humidity, the sensor will be the same color on both sides. If this happens, the device should not be used for testing.

B. The Electronic Quality Control (EQC)

1. The EQC is supplied with each instrument and must be run each day of use prior to reporting patient results. This device verifies instrument optics, reagent mixing and instrument pneumatics.
2. The EQC measures two levels of turbidimetric signals to verify the dynamic range of the instrument. The “Negative” control simulates a patient with minimal amount of platelet aggregation and a “Positive” control represents a patient with a significant amount of aggregation.
3. Procedure:
   a. The EQC Device is located in a storage port on the right side of the instrument.
   b. Choose QC by pressing the QC button from the main screen.
   c. 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.
   d. The EQC will automatically run.

e. 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.

f. If the EQC Device result is "FAIL", repeat the EQC. If the result is "PASS", continue with patient testing. If the EQC result is "FAIL" after the second analysis, use the cleaning cartridge as described in the Maintenance Section of Accumetrics manual and rerun the EQC.

g. Print result or return to the Main Screen.

C. Wet Quality Control (Level 1 and Level 2)

1. The Wet Quality Control (WQC) procedure must be performed whenever a new lot of cartridges are opened, whenever a new shipment is received or every 30 days. It can also be performed whenever a problem is suspected with the temperature indicator of a newly received lot of Test Devices, whenever a problem is suspected with the Verify*Now* System.

2. Sample Preparation:
   a. All control material should be stored at room temperature (18 to 30 °C).
   b. Do not open the vial containing the Level 2 Control pellet until immediately prior to use.
   c. Control Level 1 is ready for use as provided.

3. Wet Quality Control:
   a. Press the QC Icon key. The *Insert Cartridge* screen will display.
   b. Open the foil pouch and remove the Test Device. The Test device should only be handled by the finger grip. Verify that the humidity sensor is not the same color on both sides.
   c. 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.
   d. 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 reader. An audible beep will signal that the instrument has read the bar code, and the testing will continue.
   e. Prepare the WQC Sample.
      i. Level 1: Assay Control Level 1 is ready for use as provided.
      ii. Level 2: Remove the stopper from the tube containing the Level 2 Control diluent by twisting and pulling the cap simultaneously.
      iii. Add the Level 2 control pellet to the Level 2 control diluent tube and replace the stopper by pressing and turning simultaneously.
      iv. Invert the tube gently 5 times to mix.

f. 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.
g. The instrument will run the test and display the result.
h. Print or record the result and return to the Main Screen.
i. 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.
j. Discard the used device and quality control tube as biohazardous waste.
k. The instrument is ready to test the next sample.
l. Determine that the WQC result is within the acceptable range of values printed on the Test Device pouch provided with the test.
m. If the WQC is in control, proceed with the test of patient samples. If the WQC is out of range, follow the procedure established by your institution.

4. Recall of EQC or WQC Results:
   a. The last 100 EQC and WQC results can be recalled at any time. You may scroll by using the arrow keys on the keypad.
   b. Press the Maintenance button from the Main Screen.
   c. 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).
   d. Press the appropriate button to recall the EQC or WQC results.
   e. Press the back arrow to return to the Main Screen.

VII. SPECIAL SAFETY PRECAUTIONS

It is extremely important that care be taken in the collection, handling, and preparation of the patient's blood specimen.

Warning: Patient specimens should be handled as if they contain infectious materials, in accordance with national guidelines for Biosafety/Hazard Group 2. In the United States, the universal precautions recommended by the Department of Labor, Occupational Safety and Health Administration apply. (Occupational Exposure to Blood Borne Pathogens; final rule (29 CFR 1910, 1030) FEDERAL REGISTER, pp 64004-64182. Follow Pathology Laboratory safety policy III-01 and Auto Lab safety procedure (SH.CP.AU.gen.0005).

VIII. MATERIALS

A. Equipment and Supplies

1. Verify*Now* Instrument.
2. PRU Test Device (reagent device), box of 25 Test Devices (PN: 85225). Store at room temperature (15-30°C). Each test device contains lyophilized fibrinogen-coated beads, ADP, bovine serum albumin, PGE1, and buffer.
3. Greiner Bio-One Vacuette 2.0 mL partial fill collection tubes containing 3.2% sodium citrate, Greiner Catalog Number 454321/454322.
4. Phlebotomy supplies, including needle of 21 gauge or larger.
5. Electronic Quality Control Device provided with instrument.
6. Wet Quality Control (WQC), P/N 85047, Box of 6 Diluent Tubes and 6 Pellets. QC materials are stable at room temperature until the expiration date indicated on the tube or pellet container.

B. Reagents

1. All required reagents are contained within the individually packaged PRU Test device. Each test device contains lyophilized fibrinogen-coated beads, ADP, iso-TRAP, bovine serum albumin, PGE1, and buffer.
2. Each individually sealed test device contains the lot number and expiration date stamped on the foil pouch.
3. Once removed from its foil pouch, the test device must be handled only by the finger grip and used immediately.
4. Receipt of Shipment:
   a. When a shipment of kits is opened, check the temperature indicator located on the outside of the box.
   b. If the temperature indicator is activated, this indicates exposure to elevated temperatures and a VerifyNow Level 2 WQC should be performed.

c. If the Level 2 WQC result does not fall within the accepted range on the package insert, call Accumetrics Customer Support at (800) 643-1640.

5. Storage Temperature:

   a. Store Test Devices at 15° C to 25° C (59° - 77° F).

   b. Test Devices should remain sealed in the foil pouch until ready for use to prevent damage by humidity.

6. Reagent Quality Control:

   a. The manufacturer recommends that both WQC Level 1 and WQC Level 2 be run once each time a new lot or a new shipment of VerifyNow PRUTest kits is received or at minimum every 30 days.

IX. Calibration and Calibration Verification

A. VerifyNow PRU 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.

B. 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.

   1. 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.
   2. An audible beep will be heard when the instrument receives the required information.
   3. The user needs only to perform this action once per lot.

C. No additional calibration is performed by the user.

D. 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 above), with periodic review of QC results by the laboratory technical supervisor. Tests of platelet function are non-linear, and no additional calibration verification is required.

X. PROCEDURE – (STEP/ACTION)

A. Maintenance (refer to SH.CP.AU.frm.0235, Days Coag Maintenance)

1. The Maintenance and Setup Icon is used to setup users, change the date and time, recall QC results, network the instrument, set patient ID requirements and for troubleshooting. This function should only be performed by users with proper training and authority. Refer to the User Manual for additional information.

2. Daily
    a. Keep the surface of the instrument clean with any commonly used laboratory disinfectant.
    b. Run Electronic QC (refer to section VI.B)
3. Biweekly:
    a. Cleaning Device: Once every other week, or if the EQC Device fails twice.
        i. REMOVE THE TAPE FROM THE CLEANING DEVICE AS INDICATED. Place the Cleaning Device in the test port for 5 seconds and remove.
        ii. Dispose of the single use Cleaning Device.
        iii. Rerun the EQC. If the EQC does not pass, follow standard troubleshooting procedures.
    b. Check and clean fan filter as necessary
4. If the EQC Device becomes contaminated, wipe clean with alcohol swabs.
5. Annually: Replace the fan filter no less than yearly (see Section 9.2 of the User Manual for additional information).
6. Other than fuse replacement, the external power cord, or parts discussed above no other user-serviceable parts exist on the VerifyNow Instrument. Contact Accumetrics Technical Support at 1-800-643-1640 Option 2 if further service is required.

B. Power on the instrument*: This will initiate the following startup checks:*

1. A system program and data memory checks to ensure memory integrity.
2. A system temperature check to ensure the Test Device warming plate reaches and maintains the proper temperature.
3. A system check of proper operating voltages.
4. A system intra-communication validation.

C. Electronic Quality Control: Perform if one has not been performed within the required timeframe. The following checks are performed:

1. Instrument optics.
2. Pneumatics system that draws the sample into the Test Device and moves it into the Test Device for reaction and measurement.
3. Reagent mixing parameters and sample data acquisition.
4. Correct calibration parameters.

D. Test Procedure*:*

1. Open the foil pouch and remove the Test Device. Test Devices should only be handled by the finger grip.
2. Verify that the humidity sensor is not the same color on both sides.

3. Remove the needle's protective sheath by pulling directly up on the sheath. Do not twist the sheath as this may remove the needle.
4. 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 reader. An audible beep will signal that the instrument has read the bar code, and the test will continue.
5. At the instrument prompt, invert the sample tube at least 5 times, and insert onto the needle in the Test Device. Close instrument cover.

CAUTION: Sample is under pressure. Do not remove sample tube from Test Device. Only remove Test Device from the instrument after the test is completed.

6. The instrument will run the test and display the result in less than five minutes.
7. Record and print the sample result.
8. Open instrument cover. Remove the Test Device by grasping the device finger grip and pulling straight up. Do not remove the tube from the Test Device. Close instrument cover.
9. Dispose of the entire Test Device/sample tube in appropriate biohazard waste container.
10. The instrument is ready to test the next sample.
11. Enter the PRU (P2Y12) into the LIS.

XI. LIMITATIONS

A. General 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. Test Device Humidity Indicator for All Tests: Each Test Device contains an internal humidity sensor. If the Test Device has been degraded due to exposure to excessive humidity, a color change of the humidity indicator will be observed. The user is instructed to check the color of the indicator before each test, and to discard a Test Device where a color change is evident. The Test Device Humidity Indicator detects errors due to adverse environmental conditions. Because of the built-in humidity indicator on each VerifyNow Instrument's Test Device, it is not necessary to record the humidity of the room on a daily basis.
7. Store reagents and quality control material according to the package directions. The Test Devices can be stored either at room temperature.
8. 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.
9. 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.
10. Clopidogrel and prasugrel are pro-drugs, which are each metabolized *in vivo* to their active metabolites. The metabolism of clopidogrel occurs through a cytochrome P450-dependent pathway, while prasugrel is metabolized by carboxylesterase (hCE)-2 and other cytochrome P enzymes.[1] The antithrombotic effects of P2Y12 receptor inhibiting drugs can vary in individual patients due to differences in conversion to their active metabolites, as well as other factors.[2,3]
11. Patients with inherited platelet disorders such as von Willebrand Factor Deficiency, Glanzmann Thrombasthenia and Bernard-Soulier Syndrome have not been studied with the VerifyNow PRU Test. The VerifyNow PRU Test is not intended for use with these types of platelet disorders.
12. Patients with a known history of platelet counts <100 $x10^9$/L have not been studied.
13. 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.
14. VerifyNow PRU Test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.

B. Interfering Substances

1. Laboratory testing was performed to determine the effect of several classes of drugs on VerifyNow PRUTest results.

2. Certain drugs that inhibit platelet function affect the results of the VerifyNow PRUTest
3. Glycoprotein IIb/IIIa inhibitors abciximab, eptifibatide, and tirofiban significantly affect VerifyNow PRUTest results.
4. Cilostazol may affect VerifyNow PRUTest results. The average duration of its platelet inhibitory effect is 12 hours.
5. Drugs that affect platelet function may be detected up to 14 days after ingestion.
6. Other classes of commonly used drugs were tested with no significant effect on VerifyNow PRUTest performance, including: antioxidants, ACE inhibitor, antiarrhythmics, anticoagulants, aspirin, antidepressants, insulin, allopurinol, alcohol, beta blockers, bronchodilators, calcium channel blockers, gastrointestinal medications, betamethasone, lovastatin, NSAIDs (including COX-1 and COX-2 enzyme inhibitors), and the thyroid hormone L-thyroxine. The thrombolytic agent streptokinase showed no significant inhibition of platelet function, as measured by the VerifyNow PRUTest (see table below for details).

Interferent tested	Concentration
Triglyceride	37 µM
A3P5P21	100 µM
Acetaminophen	1.32 mM
Betamethasone	64 µM
Caffeine	306 µM
Captopril	23 µM
Catechin	86 µM
Celecoxib	8.5 µg/mL
Cilostazol	60 µM
Cimetidine	79 µM
DMSO	0.11%
Dipyridamole	20 µM
Diltiazem	15 µM
Ethanol	87 mM
Fish oil	32 mg/dL
Glucosamine HCl	9.4 µM
Low-molecular weight heparin	1.833 U/mL
Hydrochlorothiazide	20 µM
Ibuprofen	2.4 µM
Insulin	3 ng/mL
Lidocaine	51 µM
Nitroglycerin	0.1 µg/mL
Norfluoxetine	7.17 µM
Norverapamil	4.5 µM
Omeprazole	20 mg oral
Oxypurinol	99 µM
Pravastatin	56 µM
Propranolol	7.7 µM

Salicylic acid	4.3 mM
Streptokinase	400 U/mL
Theophylline	220 mM
L-Thyroxine	32 nM
α-Tocopherol	58 µM
Warfarin sodium	32 µM

7. Test performance was not affected by hematocrit values between 33-52%, or platelet count values between 119,000 -502,000/µL.
8. No significant interference was observed on samples studied with triglyceride concentrations between 41-824 mg/dL. No significant interference was observed on samples studied with cholesterol concentrations between 98-316 mg/dL.
9. No test interference was observed when samples with fibrinogen levels between 171 and 599 mg/dL were tested with the VerifyNow PRUTest.

XII. CALCULATIONS

None

XIII. INTERPRETATION

A. The VerifyNow P2Y12 assay is a whole blood assay to measure the level of platelet P2Y12 receptor blockade. Substances known specifically to block the P2Y12 receptor include the thienopyridine class of drugs, such as Plavix (clopidogrel bisulfate).

B. **Platelet Function P2Y12 (PRU)**: indicates the amount of ADP-mediated aggregation specific to the platelet P2Y12 receptor. PRU is calculated as a function of the rate and extent of platelet aggregation in the ADP channel.

C. Reference range: VerifyNow PRUTest (pre-drug): 194 – 418 PRU

D. A PRU of 208 or less is recommended for patients receiving P2Y12 anti-platelet therapy. A PRU of 237 or greater would suggest a return to baseline aggregation after the withdrawal of medication or would suggest medication resistance in a person recently initiating treatment.

E. Accumetrics provides the following table identifying the expected % inhibition threshold at specific PRU levels. The data demonstrated that PRU results have an excellent ability to discriminate 1 % inhibition result above or below a specific threshold:

% Inhibition Threshold	PRU Threshold
10%	259
20%	237
30%	214
40%	187
50%	159
60%	131

XIV. RESULT REPORTING

The VerifyNow PRU test reports results in P2Y12 Reaction Units (PRU), which report the amount of P2Y12 receptor mediated aggregation specific to the platelet, and are calculated as a function of the rate and extent of platelet aggregation in the ADP channel.

XV. TRAINING

Personnel	Training Required
Management	Read
End User	Read Perform Knowledge Check Perform Skills Assessment

XVI. REFERENCES:

A. VerifyNow Assay WQC, Package Insert, PN 14349.

B. VerifyNow PRUTest, Package Insert, PN 14438.

C. VerifyNow System User Manual, PN 14340.J.

D. SH.CP.AU.hem.0057.0002 Verify Now P2Y12 SOP

E. CLSI Guideline C28-A2.