TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	5/20/2021
Department:	Core Lab	**Due Date:**	6/20/2021

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Platelet Function - Verify Now SGMC.HG1021 v2

Description of change(s):

Section	Reason
3.1, 3.2	Added light blue top tube as acceptable tube type; Note: Samples will be labeled with a yellow dot sticker to differentiate them from other coag test specimens that can be spun.

The above change also applies to PFA-100 test (SOP already allows for use of blue tops)

This revised SOP will be implemented on June 8, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Platelet Function - Verify Now**	
Prepared by	Leslie Barrett	Date: 8/12/2020
Owner	Robert SanLuis	Date: 8/12/2020

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Platelet Function - Verify Now	Verify Now System	PRUT

Synonyms/Abbreviations
P2Y12 Inhibition, VerifyNow, Platelet Inhibition, Plavix Inhibition, PRUTest

Department
Coagulation

2. ANALYTICAL PRINCIPLE

The Verify Now System platelet function testing measures the activity of platelets. Therapies that inhibit platelet function have been used extensively to prevent the clinical complications of atherothrombosis (formation of clot). Three classes of potent anti-platelet agents, including acetalsalicylic acid (aspirin), PRUTest P2Y12 inhibitors, and glycoprotein IIb/IIIa inhibitors, have been developed. However, this laboratory will only focus on PRUTest P2Y12 inhibitors.

PRUTest device contains a lyophilized preparation of human fibrinogen coated beads and platelet agonist. PRUTest is based upon the ability of glycoprotein 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.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	Blood samples should be obtained from an extremity free of peripheral venous infusions. Collection of blood sample should be performed with care to avoid contamination by tissue factors.
Special Collection Procedures	• Use a 21 gauge or larger needle. A 21 gauge Butterfly may also be used. • First, collect a discard tube (one blue top tube, at least 2 mL). If patient has additional tests ordered, always draw the required tubes for this test first to avoid any

Component	Special Notations
	contamination. • Fill the sample tube to the black line printed half way on the tube. Do not under fill. • Collect two tubes per patient. • Gently invert the tube at least 5 times to ensure complete mixing of the contents.
Other	Do NOT place the sample in a water bath or on a rocker plate. Do **NOT** centrifuge the samples. Samples must be hand delivered to laboratory. Do NOT use the pneumatic tube system. Light blue top tubes must be identified with a yellow dot label.

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Whole Blood None
Collection Container	Preferred: Greiner Bio-One partial-fill vacuette tube with 3.2% sodium citrate Other acceptable: Light blue top tube with 3.2% sodium citrate (9:1 anticoagulant)
Volume - Optimum **- Minimum**	2 - 2 mL tubes Greiner Bio-One tubes 1 - 2 mL tube Greiner Bio-One tubes
Transport Container and Temperature	Collection container tube at room temperature
Stability & Storage Requirements	Room Temperature: 4 hours (18 – 25ºC)
	Refrigerated: Unacceptable
	Frozen: Unacceptable
Timing Considerations	Blood must equilibrate at room temperature for a minimum of 10 minutes after collection before testing.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Clotted or under-filled tubes are not accepted. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message.
Compromising Physical Characteristics	Reject hemolyzed samples and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Fresh whole blood samples are required for this test.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6)

Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
PRUTest device	Accriva Diagnostics VerifyNow System Cat. No. 85225

4.2 Reagent Preparation and Storage

Reagent	PRUTest
Container	Plastic container in a sealed foil pouch
Storage	15 - 25ºC
Stability	Test device is suitable for use until the expiration date printed on the label. Test device should remain sealed in the foil pouch until ready for use to prevent damage by humidity.
Preparation	No preparation is required.

5. CALIBRATORS/STANDARDS

VerifyNow PRUTest devices are calibrated at the factory. This calibration information is contained in the barcoded on the pouch of each device. The barcode must be scanned whenever a new lot of test devices is to be tested. If a new lot of test devices is being used, the instrument will prompt the user by displaying a barcoded icon after the test device is inserted. At the prompt, place the test device pouch in front of the barcode reader found on the left side of the instrument, so that the barcode on the pouch lines up with the barcode reader. An audible beep will be heard when the instrument receives the required information.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Electronic Control (EQC)	Accriva Diagnostics VerifyNow System Cat. No. 70068
Wet Control Levels 1 & 2	Accriva Diagnostics VerifyNow System Cat. No. 85047

6.2 Control Preparation and Storage

Control	Electronic Quality Control (EQC)
Preparation	None
Storage/Stability	Stored in the instrument

Control	Wet Control Levels 1 & 2 (WQC)
Preparation	Level 1 is ready for use. For level 2, refer to Wet Control Procedure Level 2 in this section.
Storage/Stability	Unused control material is stable until the expiration date stamped on the label when stored at 15 - 25°C. Reconstituted QC material should be used within 15 minutes.

6.2.1	**Electronic Control (EQC) Procedure**
1.	Power on the instrument. The instrument will power on and perform a self test which lasts about 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.
2.	Press the "QC" key. Wait for the image of the device to display.
3.	Remove the Electronic Quality Control (EQC) device from the storage bay on the right side of the instrument. Open cover and using the finger grip, insert the EQC device into the test device port until it clicks. The instrument will produce two audible beeps. Close the cover to the test port.
4.	The instrument will automatically proceed with the EQC test. A countdown screen will display while electronic control is in progress. When the EQC is complete the instrument will prompt the user to completely remove the EQC device from the test port.
5.	Open the cover. Remove the EQC device and return it to the storage bay. Close the cover.
6.	After the EQC device is completely removed from the port, the instrument will beep and a calculation screen will display briefly prior to displaying the final result. Wait for the electronic quality control results to display.
7.	If the instrument is operating within its specifications, PASS will display at the conclusion of the testing. In addition, numeric values will be reported for the diagnostics, along with the acceptable range for each parameter. When the EQC is complete, print the result first then press the "NEXT" key to return to the main menu.
8.	Attach the printed EQC result on the "VerifyNow EQC Log".
9.	If there is a problem detected during the EQC process and the instrument is not operating within its specifications, a FAIL message will display. The failed parameters will be indicated by an arrow to the right of the measured values. Press the "NEXT" key and perform the corrective action described. When the corrective action is completed, repeat the EQC. If diagnostic failure displays a second time, record the error code and refer to User Manual to troubleshoot.

6.2.2	**Wet Control Procedure Level 1 (WQC1)**
1.	Power on the instrument. The instrument will power on and perform a self test which lasts about 30 seconds. After the self-testing is complete, the start screen

6.2.2	Wet Control Procedure Level 1 (WQC1)
	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.
2.	Press the "QC" key. Wait for the image of the device to display.
3.	Open the foil pouch and remove the test device just before use. Hold it by the finger grip.
4.	Remove the needle's protective sheath by pulling directly up on the sheath. Do not twist the sheath, as this may remove the needle.
5.	Open the cover. Using the finger grip, insert the test device into the test device port until it clicks.
6.	If the test device is the first from a new lot, the instrument will display a bar code screen as soon as the test device is inserted into the port and the device spot code is read. Position the barcode of the test device pouch in front of the bar code scanner on the left side of the instrument so that the bar code on the bottom edge of the pouch lines up with the scanner window. Move the pouch both towards and away from the red barcode light. An audible beep will be heard when the instrument reads the information. Press the "RETRY" key if the scanner does not read the bar code. After the bar code has been scanned once, the instrument will accept all remaining test devices from that lot without displaying the bar code screen.
7.	Gently invert the diluent tube five times to mix the reagents immediately before use.
8.	Wait for the image of the tube to display, then insert the Wet Quality Control (WQC1) sample into the sample well of the test device with the rubber stopper facing downward, so that the needle fully pierces the stopper. The instrument will produce two audible beeps when the tube has been fully inserted.
9.	Close the cover to the test device port.
10.	The instrument automatically draws the sample from the vacuum collection tube into the test device, heats the sample, and proceeds with the analysis of the sample. During this time the screen will flash the test device icon, indicating that the sample is processing. Do not open the cover until the test has completed and a result displays. A calculator will display when the test is near completion. **Caution**: The sample is pressurized during parts of the test. Never remove the sample tube or test device during the test. To abort a test, press the "BACK" key. Wait for the prompt before removing the test device and tube.
11.	When the result displays, print and document it on the "VerifyNow Maintenance Log." Record the acceptable range (copy from the cartridge cover). Check the appropriate box to indicate 'accept' or 'fail' and attach the printout to the 2nd page.

6.2.2	Wet Control Procedure Level 1 (WQC1)
12.	Open the cover. Remove the test device and tube together in one piece by grasping the test device finger grip and pulling straight up. Never separate the tube from the test device. Close the cover. Discard the test device and tube in a biohazard waste.

6.2.3	Wet Control Procedure Level 2 (WQC2)
1.	Prepare WQC Level 2: a. Inspect the pellet. It should appear pink. If the pellet appears too small, red or is stuck to the vial, discard and use a new pellet. b. Immediately before use, open the vial containing the pellet. Remove the cap from the diluent tube by twisting and pulling the cap simultaneously. c. Hold the diluent tube vertically. Then, invert the vial containing the pellet so that the pellet falls into the diluent tube. Ensure the pellet does not stick to the side of the diluent tube, as it will not reconstitute properly. d. Replace the cap on the diluent tube by pressing and turning simultaneously. Immediately after replacing the cap, gently invert the tube five times to mix the reagents. **Control material should be used within 15 minutes of reconstitution**. **Note**: If the reconstituted control is not used immediately, gently invert the tube five times to mix the reagents again just before use.
2.	Wait for the "Insert Tube" image to display, then insert the WQC2 sample into the sample well of the test device with the rubber stopper facing downward so that the needle pierces the stopper. The instrument will produce two audible beeps when the tube has been fully inserted.
3.	Close the cover to the test device port.
4.	The instrument automatically draws the sample from the vacuum collection tube into the test device, heats the sample, and proceeds with the analysis of the sample. During this time the screen will flash the test device icon, indicating that the sample is processing. Do not open the cover until the test has completed and a result displays. A calculator will display when the test is near completion.
5.	When the result displays, print and document it on the "VerifyNow Maintenance Log." Record the acceptable range (copy from the cartridge cover). Check the appropriate box to indicate 'accept' or 'fail' and attach the printout to the 2nd page.
6.	Open the cover. Remove the test device and tube together in one piece by grasping the test device finger grip and pulling straight up. Never separate the tube from the test device. Close the cover. Discard the test device and tube in a biohazard waste.

6.3 Frequency

The Electronic Quality Control (EQC) is run once per day on each instrument. This reusable device verifies instrument optics, pneumatics and reagent mixing.

The Wet Control Levels (WQC) must be run once a week on each instrument.

6.4 Tolerance Limits and Criteria for Acceptable QC

Test Device Internal Controls: 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 or Low-Level Internal Control performs a test for non-specific aggregation. During the active phase of the test, the Positive or High-Level Internal Control channel monitors the reaction and calculates clinical control units, which must fall within specified limits. A failure of either internal control results in an error message by the Verify Now Instrument, which prevents the reporting of an inaccurate result.

The test device internal controls can detect failures of the reagent system due to improper storage or handling conditions. The internal controls will also flag an improperly collected or mishandled blood sample, or a blood sample with certain types of interfering substances. The test device internal controls detect errors from the reagent system, adverse environmental conditions, and additional types of operator errors.

Wet QC Levels 1 and 2 are used for verifying the integrity of the Verify Now System. In the Verify Now Tests, Level 1 is representative of a sample with platelet inhibition, and Level 2 is representative of a sample with no platelet inhibition.

EQC	
IF……	**THEN……**
EQC fails	Perform a cleaning explained in section 8.2, then repeat the EQC
EQC fails again	Call Technical Support if EQC does not pass after three attempts. Also notify the supervisor.

WQC	
IF……	**THEN……**
Internal Control Fails	Run WQC Levels 1 and 2 to rule out degradation of test device reagents as the cause of the failure
WQC fails	Call Technical Support if WQC fails. Also notify the supervisor.

6.5 Documentation

- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Accriva Diagnostics VerifyNow system

7.2 Equipment

Printer (Cat. No. 85021)

7.3 Supplies

Preventive Maintenance Kit (Cat. No. 85062)
Fan Filter (Cat. No. 37056)

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Test Run
1.	After performing the required QC, press the next key to go back to the main menu and press the test key. Enter patient ID. To enter a letter for patient ID, press the A key. Use ↑ or ↓ arrows to scroll through the text option screens. At the desired screen, press ← or → to move to the desired character. Press the ABC key to select the character.
2.	After the patient ID is entered, press the Next key. The earlier patient ID screen will display. Press the Next key again to continue. The screen will prompt to insert the test device.
3.	Open the foil pouch and remove the test device just before use. Hold it by the finger grip.
4.	Remove the needle's protective sheath by pulling directly up on the sheath. Do not twist the sheath, as this may remove the needle.
5.	Open the cover. Using the finger grip, insert the test device into the test device port until it clicks.
6.	Gently invert the sample tube five times to mix the reagents immediately before use.
7.	Wait for the insert tube icon to display, then insert the sample into the sample well of the test device with the rubber stopper facing downward so that the needle pierces the stopper. The instrument will produce two audible beeps when the tube has been fully inserted.
8.	Close the cover to the test device port.
9.	The instrument automatically draws the sample from the vacuum collection tube into the test device. It then heats the blood to 37° C for a period of time specific to each test, and proceeds with the analysis. During this time the screen will flash indicating that the sample is processing. Do not open the test port cover until the test is complete. A calculator will display when the test is near completion. **Caution**: The sample is pressurized during parts of the test. Never remove the sample tube or test device during the test. To abort a test, press the back key. Wait for the prompt before removing the test device and tube.
10.	It typically takes 3 to 5 minutes for the test to complete.
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. Discard the test device and tube in a biohazard waste.

8.2	Cleaning Device
1.	Small amounts of dust and debris may build up on the pneumatic port connection of the instrument. Cleaning Device consists of a clear plastic component with an adhesive strip. It removes debris from a pneumatic port connection inside the test device port. **Caution:** Excessive use of cleaning devices can damage the instrument. Cleaning more often than once a week is not recommended, unless prompted at the display screen.
2.	Locate the cleaning device pack, and remove cleaning device from pouch.

8.2	Cleaning Device
3.	Grasp the cleaning device using the finger grip and remove the clear plastic tape. Discard the tape.
4.	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.
5.	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.
6.	Remove the cleaning device completely from the test device port and inspect it. Discard the device. The cleaning device is for single use only.
7.	Repeat using another cleaning device if, upon inspection, there is visible dust and debris.

8.3	Replace the Fan Filter
1.	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 must be performed to avoid overheating of the instrument.
2.	Power off the instrument.
3.	The fan filter is held in by a press fit retainer. Using a small tool, gently pull from the center of the filter retainer.
4.	Remove the fan filter and inspect it for dust accumulation.
5.	If necessary, replace it with a new filter.
6.	Gently replace the fan filter and plastic filter retainer. Do not position the instrument so that airflow to the fan is obstructed.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The PRUTest reports patient results in P2Y12 Reaction Units. P2Y12 Reaction Units report the amount of P2Y12 receptor mediated aggregation specific to the platelet and are calculated as function of the rate and extent of platelet aggregation in the ADP channel.

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

P2Y12 Reaction Units (PRU)

10.4 Clinically Reportable Range (CRR)

0 – 999 PRU

10.5 Review Patient Data

Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

If ……	Then ……
The result appears as the following message: Error – Measurement Timeout	1. Power the instrument off. Wait 10 seconds, and then power it on. 2. Perform an EQC test. 3. If the EQC is OK (PASS), run a Wet QC Level 2 and verify the result falls within expected range. If so, re-test the patient sample. 4. If the same error message occurs, report the result with LIS code PTERR 5. If EQC fails or the WQC produces an error, call Technical Support.
The instrument is not working at all	Perform a device cleaning as described in section 8.2 and then run EQC before running patient.
The device still not working	Call Technical Support. Also notify the supervisor.

Message	Code
Error – Measurement Timeout. 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 of abciximab (ReoPro) and up to 48 hours for eptifibatide (Integrillin) and tirofiban (Aggrastat). The platelet function recovery times varies among individuals and is longer for patients with renal dysfunction.	PTERR

Manually enter result in the LIS using function MEM and worksheet code **WCO** for WOMC or **SCO** for SGMC.

11. EXPECTED VALUES

11.1 Reference Ranges

194 – 418 PRU

11.2 Critical Values

None established

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS:

PRU = P2y12 reaction units. A reference range is established at 194-418 PRU for patients not receiving P2Y12 inhibitors. PRU values less than the low end of the reference range are consistent with P2Y12 inhibitor effect.
The GRAVITAS trial showed achievement of on-clopidogrel reactivity <208 PRU at 12 to 24 hours after percutaneous coronary intervention or during follow-up was associated with a lower risk for cardiovascular events [Circulation, Aug 29, 2011].
This test should not be used for patients who have received Glycoprotein IIb/IIIa inhibitor drugs within 14 days [ReoPro] or 48 hours [Integrilin and Aggrastat].
Platelet function recovery time will vary among individuals and is longer for patients with renal dysfunction.

12. CLINICAL SIGNIFICANCE

P2Y12 inhibitos are a class of therapy that has significant antiplatelet effect by inhibiting adenosine diphosphate (ADP)-mediated platelet activation. Platelet activation by ADP plays a key role in the development of arterial thrombosis. When secreted by activated platelets from storage granules, the ADP activates additional platelets in circulation through two G protein-coupled P2 receptors, P2Y1 and P2Y12 inhibitors irreversibly inhibit ADP binding to the P2Y12 receptor on the platelet surface. By blocking this receptor, these agents interfere with additional platelet activation, degranulation, and – by inhibiting the modification of the glycoprotein IIb/IIIa receptor – aggregation.

The Verify Now PRUTest is a whole blood test used in the laboratory or point of care setting to measure P2Y12 receptor blockade. The test incorporates the agonist ADP to activate platelets. The Verify Now PRUTest also uses PGE1 to increase intra-platelet cAMP and reduce the contribution of the P2Y1 receptor on activation. This makes the test more specific for the effects of ADP on the P2Y12 receptor. It measures platelet function based upon the ability of activated platelets to bind to fibrinogen. Fibrinogen – coated micro-particles aggregate in whole blood in proportion to the number of activated platelet glycoprotein IIb/IIIa receptors; and if the P2Y12 inhibitor has produced the expected anti-platelet effect,

such aggregation will be reduced. The Verify Now PRUTest reports the extent of platelet aggregation in P2Y12 reaction units (PRU). PRU reports the amount of ADP-mediated aggregation specific to the platelet P2Y12 receptor, and is calculated as a function of the rate and extent of platelet aggregation in the ADP channel.

13. PROCEDURE NOTES

- **FDA Status:** Approved/Cleared
- **Validated Test Modifications:** None
- Do not insert fingers or anything other than a test device, cleaning device or EQC device into the test device port of the Verify Now instrument.
- The test device sample well contains a sharp needle. Do not insert fingers or anything other than a sample tube into the sample well.
- Do not remove sample tubes from used test devices. Discard used test devices and attached sample tubes as a single unit.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0 – 999 PRU

14.2 Precision

Simple and complex precision were determined according to CLSI precision guidelines, using three lots of VerifyNow PRUTest devices. For complex precision, whole blood was drawn from volunteer donors and duplicate measurements in two runs per day were performed over 20 days.

Complex Precision Statistics as Defined by CLSI							
Complex Precision Whole Blood			Within-Run (simple)			Total	
Description	Days	Results	Mean	SD	CV%	SD	CV%
Male Age 48	20	80	284	21.4	7.5	21.4	7.5
Male Age 29	20	80	175	9.2	5.3	17.5	10

Preliminary (Simple) precision was determined for the VerifyNow PRUTest wet quality control Level 2. Three lots of test devices were each tested 20 times using a single lot of control.

Lot to Lot Cartridge Variation				
Device Lot	N	PUR Mean	SD	CV%
1	20	333	12	3.7
2	20	284	11	4.1
3	20	351	13	3.6

14.3 Interfering Substances

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

- Certain drugs that inhibit platelet function affect the results of the VerifyNow PRUTest.
- Glycoprotein IIb/IIIa inhibitors abciximab, eptifibatide, and tirofiban significantly affect VerifyNow PRUTest results.
- Cilostazol may affect VerifyNow PRUTest results. The average duration of its platelet inhibitory effect is 12 hours.
- Drugs that affect platelet function may be detected up to 14 days after ingestion.
- 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.
- Test performance was not affected by hematocrit values between 33-52%, or platelet count values between 119,000 -502,000/μL.
- 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.
- No test interference was observed when samples with fibrinogen levels between 171 and 599 mg/dL were tested with the VerifyNow PRUTest.

14.4 Clinical Sensitivity/Specificity/Predictive Values

The VerifyNow PRUTest is formulated to have greater specificity for platelet aggregation mediated by the P2Y12 receptor than the P2Y1 receptor, both of which are activated by ADP. Thus, LTA using ADP as the agonist is affected by both platelet ADP receptors P2Y1 and P2Y12.

Since clopidogrel acts only on the P2Y12 receptor site, LTA has a non-specific aggregation artifact due to P2Y1 mediated aggregation that is not seen in the VerifyNow PRUTest.

To accomplish the goal of having a test with reduced non-specific aggregation, the VerifyNow PRUTest uses an additive (PGE1) in addition to ADP to make the test more sensitive and specific for the effects of ADP mediated by the P2Y12 receptor.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Specimen Acceptability Requirements (Lab policy)
5. Repeat Testing Requirements (Lab policy)
6. VerifyNow EQC Log (AG.F303)
7. VerifyNow Maintenance Log (AG.F304)
8. VerifyNow Patient Log (AG.F325)
9. Current package insert for Verify Now system

17. REFERENCES

1. Accumetrics Verify Now System user manual, revised 03/2013
2. Accumetrics Verify Now System Wet QC Package Insert, revised 10/2019
3. Accumetrics Verify Now System PRUTest device Package Insert, revised 06/2019

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes WAH.G928.1		
1	5/17/21	3.1, 3.2	Added light blue top tube	L Barrett	R sanLuis

19. ADDENDA

None