VerifyNow® System

Implementation Guide

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Preface

Introduction

The validation studies described in this section are dependent on requirements approved and dictated by the Laboratory Medical Director and the Accrediting Organization for implementing a new lab instrument or assay. Please consult your local governing agency on best practices when validating diagnostic medical equipment, as such best practices may not be reflected in the descriptions set forth in this section.

The Centers for Medicare and Medicaid Services (CMS) administers the Clinical Laboratory Improvement Amendments (CLIA) which regulates all facilities that perform testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

Many private agencies have emerged to promulgate standards for laboratory best practices. In addition, these agencies perform site-visits or inspections to the facility to observe and document compliance of laboratory standards. Currently, these agencies include: The College of American Pathologists (CAP), The Joint Commission (TJC - The Joint Commission on the Accreditation of Healthcare Organizations - or formerly known as JCAHO), and the Commission on Laboratory Accreditation (formerly known as COLA). These inspecting agencies also offer services to U.S. military hospital laboratories. State governments have a strong role in laboratory standards as well. Each State's Department of Health manages the CLIA branch for that region. The State CLIA office can set the standards for laboratories in their jurisdiction and also inspect the testing facility. While the national office of CLIA has published their standards, each individual State CLIA branch can modify those regulations to more stringent standards and hold the testing facilities in their State to local guidelines.

CMS has directed that upon purchasing any new analyzer, immediate testing for patient management is not permitted. Regardless of manufacturer's claims or warranties, a series of quality assurance steps must be conducted to validate instrument performance and ensure analytes are reported with accuracy and precision. These implementation procedures are both essential from a Regulatory perspective and are necessary to assure diagnoses and therapeutic maneuvers remain consistent based on results analyzed from values produced from the new instrument.

Before a new analyzer is used for reporting patient results, the validation and verification of instrument performance must be completed and approved by the Medical Director named on the facility's CLIA license, issued by CMS. If the instruments are operating under the Clinical Laboratory's CLIA license, the laboratory Point of Care Coordinator (POCC) and/or the Laboratory Medical Director is required to oversee the validation process. If any department holds their own independent license to perform testing, they must comply with the standards set by the Regulatory inspecting agency indentified on the CLIA application.

As healthcare facilities continue to use departmental cross-training to streamline operations, the limits of professional boundaries becomes less defined. Specific to POC instruments, regardless of who manages this traditional laboratory diagnostic test, diligent attention to a sound Quality Management System and adherence to regulatory compliance guidelines is essential in providing accurate results yielding quality patient care.

A Laboratory Quality Management System (QMS) is a sequential integration of policies and processes that transform a physician's order into laboratory information. The objectives of QMS are to provide quality accurate diagnostic test results and reduce the potential for medical error that wastes resources and harms patients.

To assist in achieving these objectives, Accriva has developed several tools to assist when implementing VerifyNow. These tools include: Operator Training documents and Instrument Validation Templates. The Operator Training documents are designed to allow the POCC, Laboratory, Clinical Department or Physicians Office Lab (POL) to adapt the information to reflect their unique testing environment. The Instrument Validation Templates have been designed to allow the data to be sent to Technical Support for analysis.

Pre-Implementation Checklist

Facility: _____

Task	Action Required	Date Completed
Receipt of VerifyNow Instrument & Printer	Instrument(s), printer(s) and all cords are present	
Bio-Med Inspection	Assure Bio-Med inspection has been completed	
Supplies	Order and confirm receipt of sufficient amount of each device type for validation and training	
Wet Quality Control (WQC) Material for validation	Order and confirm receipt of sufficient amounts of WQC material for validation and training	
Supplies for Sample Collection	Order and confirm receipt of Greiner Tube & waste tube, confirm use of 21 gauge needle (butterfly may be used) or larger for venipuncture sample collection	
Support Documents for Implementation/Training	Documents available on website to assist with validation/ implementation of new test(s)	
Operators Training	Select individuals for "Train the Trainer" sessions	
Sample Collection Training	Schedule training for staff collecting samples, i.e. phlebotomy or nurses	
Training Area	Designate training areas for each Unit away from any patient treatment areas	
Training Materials	The Skills Checklist, Training Checklist, Sample Collection Checklist, and Competency Test have all been approved by the appropriate individuals for use	
Training Log Sheets	Training Log Sheets are available	
Additional Equipment for Training is available	Equipment: Gloves in various sizes, gauze, surface protectors, Bio-hazard disposal containers, "Sharps" containers, sterilizing wipes, and non-hazardous waste disposal units	

Operator Training and Competency Certification

Overview

Initial training on the VerifyNow PRUTest is required by all US-based regulatory bodies. This should entail a complete review of the department's Policy and Procedures Manual with respect to the VerifyNow instrument and all applicable testing. Documentation of training can be accomplished by the operator participating in a written test after review of the Manual and certified with a Skills Checklist. The Skills Checklist should include: sample collection and handling, performing the analysis, reporting results, performing Quality Control (QC) and the location of the Policy and Procedures Manual.

Final validation of competency can be demonstrated by successful testing of an unknown sample.

Continued competency certification is also an annual requirement and the same steps are utilized to satisfy this regulation.

These generic documents are designed to be modified by each site to conform to the site's requirements.

Available As Word Documents:

- (3b & 3c) **Competency Assessment**
- (3d) **Operator Training Checklist**
- (3e) **Sample Collection Training Checklist**

Training Log

Facility Name: _____

Department: _____ Date: _____

Trainer: _____

Circle Type of Training: **Initial** **Semi-annual** **Annual**

Name (print)	Signature	OID*

*OID is Operator Identification

Competency Assessment

Person Evaluated: _____ Date: _____

Evaluator Name / Title: _____

MARK YES, NO OR N/A	
	The operator has successfully completed the training program and this is documented on the VerifyNow System Training Checklist.
	Observation of all phases of testing show that all written steps of the procedure are followed without deviation.
	Specimens are collected and handled according to written procedures.
	Instrument function checks are performed and documented according to written procedures
	Patient test results are recorded and reported according to protocol.
	The operator knows Electronic Quality Control (EQC) and WQC required frequency. Results are reviewed when performed. If results are out of range, the operator corrects the problem before testing patient specimens.
	When problems arise, the operator knows how to assess the situation and does what is required to resolve the problem.
	The operator documents remedial actions associated with QC, QA, and instrumentation.
	The operator recognizes system failures, unacceptable QC and calibration checks, and inconsistent or erroneous patient test results.
	The operator contacts the appropriate person when questions arise concerning testing and/or reporting results.

Approved By: _____ Date: _____

Competency Tests

Example Competency Quiz #1

(For customers running the VerifyNow Aspirin Test and PRUTest®. This quiz can be modified for customers running other VerifyNow tests.)

1 **What is the range of time when a blood sample is valid for a VerifyNow Aspirin Test?**

a. Wait 30 minutes after draw with a maximum time of up to 4 hours after collection.

b. Wait 60 minutes after draw with a maximum time of up to 4 hours after collection.

c. Wait 10 minutes after draw with a maximum time of up to 6 hours after collection.

2 **What is the range of time when a blood sample is valid for a VerifyNow PRUTest?**

a. Wait 60 minutes after draw with a maximum time of up to 4 hours after collection.

b. Wait 10 minutes after draw with a maximum time of up to 2 hours after collection.

c. Wait 10 minutes after draw with a maximum time of up to 4 hours after collection.

3 **Should I refrigerate the blood sample tubes?**

a. Yes for only up to 4 hrs

b. Yes for only up to one hour

c. No

4 **The VerifyNow fan filter should be checked and cleaned if necessary every other week.**

a. True

b. False

c. There is not a fan filter

5 **When do you run an electronic quality control (EQC)?**

a. Daily. Instrument will prompt if needed.

b. One per lot change. Instrument will prompt if needed.

c. Every eight hours. Instrument will prompt if needed.

6 **Which blood collection tubes should you use for VerifyNow Aspirin Test?**

a. Blue top – Sodium Citrate, partial fill

b. Purple Top – EDTA

c. Blue top – any Sodium Citrate tube is OK

Competency Tests (Continued)

Example Competency Quiz #1 (Continued)

(For customers running the VerifyNow Aspirin Test and PRUTest. This quiz can be modified for customers running other VerifyNow tests.)

7 **When drawing for a Complete Blood Count (CBC) at the same time, in what sequence does it go?**

a. Complete Blood Count (CBC) is drawn last

b. CBC is drawn first

c. It doesn't matter when the CBC is drawn

8 **Which needle size should be used?**

a. 23 Gauge

b. 21 Gauge or larger

c. It does not matter

9 **Why is it important to fill the correct amount of blood?**

a. To ensure enough platelets to test

b. Ratio of anticoagulant to blood is important

c. It really does not matter

10 **How many times do you need to invert the sample collection tube?**

a. 5 times

b. Once

c. Twice

d. Four times

Competency Tests (Continued)

Example Competency Quiz #1 – Answer Key

1. **A**
2. **C**
3. **C**
4. **A**
5. **A** (may be different depending on lab requirements)
6. **A**
7. **A**
8. **B**
9. **B**
10. **A**

Competency Tests (Continued)

Example Competency Quiz #2

(For customers running the VerifyNow Aspirin Test and PRUTest. This quiz can be modified for customers running other VerifyNow tests.)

1. Which blood collection tubes should you use for VerifyNow Aspirin Test or PRUTest?

2. Where is an appropriate venipuncture site?

3. For a venipuncture, how many tubes do you collect? Which one do you use? Why?

4. With an indwelling catheter, how much blood is discarded before filling the collection tube? Why?

5. When drawing for a CBC at the same time, in what sequence are the tubes drawn?

6. Which needle size should be used?

Competency Tests (Continued)

Example Competency Quiz #2 (Continued)

(For customers running the VerifyNow Aspirin Test and PRUTest. This quiz can be modified for customers running other VerifyNow tests.)

7. How much of the tube should be filled?

8. Why is it important to fill the correct amount of blood?

9. How many times do you invert the tube?

10. Why is it important to label the time of blood draw?

11. Do you refrigerate the tubes?

Competency Tests (Continued)

Example Competency Quiz #2 – Answer Key

1. **Which blood collection tubes should you use for VerifyNow Aspirin or PRUTest?**

   Partial Fill Sodium Citrate, 2mL, 13 × 75mm, safety twist cap.

2. **Where is an appropriate venipuncture site?**

   Obtain blood sample from an extremity free of peripheral venous infusions. The median antecubital and cephalic veins are most commonly used. Avoid scarred areas, thrombosed veins, bruised areas, the arm on the side of a prior mastectomy, the arm with an A-V shunt (dialysis patients), and the same side of the body as a recent IV site.

3. **For a venipuncture, how many tubes do you collect? Which one do you use? Why?**

   Collect two tubes. Always draw a discard tube first containing at least 2mL. This is because there may be activated platelets in the first sample that will alter the test results.

4. **With an indwelling catheter, how much blood is discarded before filling the collection tube? Why?**

   Discard the first 5 mL from an indwelling catheter to clear the line. Then, collect tube.

5. **When drawing for a CBC at the same time, in what sequence does it go?**

   If you need to draw for a CBC, draw that tube last.

6. **Which needle size should be used?**

   Use a 21 gauge needle or larger. It is OK to use a butterfly as long as it is 21 gauge.

7. **How much of the tube should be filled?**

   Fill to the black line that appears at one-half of the tube. It should fill automatically but may slow down as it approaches the fill line. Do not be in a hurry to pull it off.

8. **Why is it important to fill the correct amount of blood?**

   An under-filled tube will not be sufficient to run the test because the ratio of anti-coagulant will be off.

9. **How many times do you invert the tube?**

   Make sure you gently invert the tube 5 times as soon as you pull it off the needle hub. This mixes the blood sample with the anticoagulant and ensures that microscopic clotting does not occur within the first few seconds. Do not shake the tube vigorously!

10. **Why is it important to label the time of blood draw?**

    The VerifyNow Aspirin Test and PRUTest are time sensitive. They can only be assayed up to 4 hours from collection.

11. **Do you refrigerate the tubes?**

    Do not refrigerate samples once drawn. They are kept at room temperature.

Competency Tests (Continued)

Example Competency Quiz #3

1. When do I run a wet quality control? Where do I look to find the control level range to compare with the WQC result?

2. Should I refrigerate the blood sample tubes?

3. What is the range of time when a blood sample can be used for the VerifyNow Aspirin Test? For the VerifyNow PRUTest?

4. When do I need to scan the barcode on the front of the test device pouch?

5. TRUE or FALSE? It is OK to remove the sample tubes from the test device after use?

6. How do I display an earlier patient result that I forget to record at the conclusion of the test?

7. What is a cleaning device and when would I use it?

8. If a troubleshooting message appears, what do I do?

Competency Tests (Continued)

Example Competency Quiz #3 – Answer Key

1 **When do I run a wet quality control (WQC)? Where do I look to find the control level range to compare with the WQC result?**

Run a level 2 WQC test 1) before the first use of each new lot or shipment of test device kits; 2) during troubleshooting to resolve unexpected events; 3) when the VerifyNow Aspirin Test device kit temperature indicator show exposure to elevated temperatures; or 4) WQC Level 1 & 2 every 30 days (recommended for the VerifyNow PRUTest). The control level range is printed on the test device pouch.

2 **Should I refrigerate the blood sample tubes?**

Do not refrigerate samples once drawn. They are kept at room temperature.

3 **What is the range of time when a blood sample can be used for the VerifyNow Aspirin Test? For the VerifyNow PRUTest?**

The VerifyNow Aspirin and P2Y12 Tests are time sensitive. Refer to the following table.

Test	Wait Time	Test Window
Aspirin	30 min	30 min to 4 hrs
PRUTest	10 min	10 min to 4 hrs

4 **When do I need to scan the barcode on the front of the test device pouch?**

A. Lot-specific calibration information and the device expiration date are contained in the bar code on the pouch of each test device. The bar code must be scanned whenever a new lot of test devices are to be used.

5 **TRUE or FALSE? It is OK to remove the sample tubes from the test device after use?**

FALSE. Never remove sample tubes from used test devices. Handle test devices and sample tubes as biohazard material, and discard used devices/tubes as single units in an appropriate manner.

6 **How do I display an earlier patient result that I forget to record at the conclusion of the test?**

The instrument stores the last 150 patient results in memory. Go to the Patient Results log from the main menu by pressing the Retrieve Results  key. Patient information can be retrieved by date and time or by patient identification, depending on the instrument setting.

7 **What is a cleaning device and when would I use it?**

A single use, disposable cleaning device removes small amounts of dust and debris that may build up on the pneumatic port connection of the instrument. It consists of a clear plastic component with an adhesive strip (NOTE: follow instructions on device to remove tab to expose adhesive tape prior to use). Approximately every other week, use the cleaning device to remove debris from the pneumatic port connection. This frequency can be adjusted based on room conditions. Message to use cleaning device may appear on screen for troubleshooting instruction.

8 **If a troubleshooting message appears, what do I do?**

Follow the instructions on the screen. Refer to the Troubleshooting section of the user manual for more detailed instructions.

Competency Tests (Continued)

Suggested Questions & Answers to Design Competency Quizzes and Assessments

Sample Collection and Handling

Q **You must always discard at least 2 mL of blood when drawing a venipuncture sample for the VerifyNow Test.**

A True

Q **What tubes can you draw as a discard tube before the VerifyNow Test?**

A Another sodium citrate (blue top), a blood culture or a red/white/clear top (no additive).

Q **What type of tube must be used with this system?**

A Greiner partial draw tube.

Q **How do you know when there is enough sample in the Greiner tube?**

A The tube fills to the small black line that is about halfway up the tube.

Q **Can you draw a CBC before a Sodium Citrate tube that is going to be used for platelet testing?**

A No, never.

Q **Describe the proper method for having a Registered Nurse (RN) draw from a line for these tests.**

A The line must be cleared with a 5 mL discard, and then the 2 mL drawn for the VerifyNow Test. The blood must be immediately placed in the tube, and the tube mixed gently at least 5 times. If a CBC tube is to be filled, it must be filled after the VerifyNow tube.

Q **Is it recommended that you place the tube on a rocker before testing?**

A No, never

Q **When would you refrigerate a tube for the VerifyNow Test?**

A Never

Q **When would you centrifuge a tube for the VerifyNow Test?**

A Never

Q **Samples that are going to be used for platelet testing should be drawn with a needle no smaller than _____**

A 21 gauge.

Q **Should you shake the tubes immediately after drawing to ensure proper mixing?**

A No. The tubes should be gently mixed 5 times.

Q **If the tech is not available, should the tubes for platelet function testing be placed on the rocker?**

A No, the tube should be placed upright in a rack at room temperature.

Competency Tests (Continued)

Suggested Questions & Answers to Design Competency Quizzes and Assessments

General Test Information

Q **How do you enter the calibration information into the VerifyNow instrument?**

A You hold the bar code on the device package to the bar code scanner.

Q **What do you know it is time to do when you have to read in a bar code?**

A This indicates that a new lot is in use. You should make sure that a Level 2 WQC has been run for Aspirin Test and Level 1 & 2 for PRUTest.

Q **If you receive in a shipment of assay devices and the Aspirin Test temperature indicator located on end of box has turned dark, what should you do?**

A Run a Level 2 control. If this is not in range, notify Technical Support.

Q **Where is the toll free hotline number for Accriva found?**

A On the sticker on the side of the instrument.

Q **How do you prepare the Level 1 WQC?**

A Mix the tube gently 5 times.

Q **How do you prepare the Level 2 WQC.**

A Open the diluent tube and pellet tube and pour the pellet into the tube, making sure that it does not stick on the side of the tube. Mix it gently 5 times. Run it within 15 minutes.

Q **Where do you find the ranges for Levels 1 and 2 WQC?**

A On the device pouch.

Q **How often should a cleaning device be used for preventative maintenance?**

A Every other week.

Q **What should you do with the sample tube just before placing on the device?**

A Mix gently 5 times.

Q **How does the instrument know what calibration information to use for each device?**

A The information is read from the spot code on each device.

Q **When is it safe to remove the sample tube from the test device?**

A The sample or WQC tube should never be removed from the device.

Q **Can you run a patient sample in the QC test mode?**

A No, if you do not choose the correct patient sample mode the instrument will not report a result.

Competency Tests (Continued)

Suggested Questions & Answers to Design Competency Quizzes and Assessments

VerifyNow Aspirin Test

Q **Aspirin affects platelet function by irreversibly inhibiting the _____.**

A Cox-1 enzyme.

Q **The VerifyNow Aspirin Test uses _____ to activate the platelets.**

A Arachidonic Acid

Q **The VerifyNow Aspirin Test must not be tested until _____ have passed from the time of blood draw.**

A 30 minutes

Q **The VerifyNow Aspirin Test must be assayed within _____ of the blood draw.**

A 4 hours

Q **What units are used to report the VerifyNow Aspirin Test Results?**

A ARU

Q **What does ARU stand for?**

A Aspirin Reaction Unit

Q **The result in ARUs that shows platelet dysfunction consistent with Aspirin ingestion is _____.**

A less than 550.

Q **When you look up a patient result, what letter is used to signify that the result is for the VerifyNow Aspirin Test?**

A The letter “a” appears by the result.

Q **Why do IIb/IIIa inhibitors interfere with the VerifyNow Aspirin Test?**

A Normal platelet function cannot be observed in the internal control channel.

Competency Tests (Continued)

Suggested Questions & Answers to Design Competency Quizzes and Assessments

VerifyNow PRUTest

Q **Plavix (thienopyridine class of drugs) inhibits the _____ receptor on platelets.**

A P2Y12 ADP

Q **What is the platelet agonist in the VerifyNow PRUTest?**

A ADP

Q **What is added to minimize the contribution of the P2Y1 receptor to the VerifyNow PRUTest?**

A PGE1

Q **The VerifyNow PRUTest must not be tested until _____ have passed from the time of blood draw.**

A 10 minutes

Q **The VerifyNow PRUTest must be tested within _____ of the blood draw.**

A 4 hours

Q **What units are used to report the VerifyNow PRUTest results?**

A PRU

Q **What does PRU stand for?**

A P2Y12 Reaction Units

Q **Why do IIb/IIIa inhibitors interfere with the VerifyNow PRUTest?**

A Normal platelet function cannot be observed in the internal control channel.

Q **When you look up a patient result, what letter is used to signify that the result is for the VerifyNow PRUTest?**

A The letter “y” appears by the PRU result.

Operator Training Checklist

Facility: _____ Date: _____

Name of Operator/Trainee: _____

Trainer / Qualifications: _____

Products Trained:

☐ **Aspirin Test** ☐ **PRUTest**

Setup (Refer to User Manual)	
	Instrument components: • Test Device Port and Cover • Display Screen • Icon Keys • Keypad • Power On Indicator • On/Off Switch • EQC Device Storage Bay • Barcode Reader Window • Fuse Compartment • Power Cord
	Explain importance of instrument placement (clean, firm, level benchtop; free of excessive vibration; avoid area next to a source of heat, air conditioning or in direct sunlight; or under incandescent lighting).
	Set date and time.
	EQC frequency: (determine frequency and show how to set).
	Patient ID: (Yes or No) **Length:** (if yes).

Test Device (Refer to User Manual)	
	Device components: • Finger Grip • Protective Sheath • Sample Well • Needle • Staging Well • Mixing Chambers / Detection Wells
	Storage requirements (room temp storage 2-25°C or 36-77°F for Aspirin; 15-25°C or 59-77°F for PRUTest - keep in sealed foil pouch until ready to test. PRUTest device should be used within 10 hours of opening pouch.
	Sample tube needle (CAUTION: Never remove sample tube from test device!).
	Spot Code: on each test device (lot, test type, expiration date linked to lot number).
	Bar Code: on test device pouch; calibration values in bar code; expiration date of lot number.

Operator Training Checklist (Continued)

Sample Collection and Handling (Refer to package insert)	
	Review tube types and requirements. Aspirin and PRUTest: Sodium Citrate Greiner Vacuette 2 mL partial fill tubes. Discuss errors with inappropriate tubes.
	Review sample collection: • 21 gauge or larger needle (i.e., 20 gauge); clean stick (platelet testing). • **GENTLY** mix 5 x with complete inversions immediately upon collection. • Use discard tube. For PRUTest or Aspirin, the discard tube may be a blood culture, sodium citrate, or white top tube or tube with no additive. It may NOT be a tube containing EDTA (purple top). ☐ Store at room temperature. Do not freeze or refrigerate samples. ☐ Avoid hemolysis and contamination by tissue factors. ☐ Do not test sample if there is any evidence of clotting. • Redraw sample if there is evidence of hemolysis in any other centrifuged tube that was collected at the same time.
	Pneumatic tube transport is not recommended.
	Emphasize handling and time requirements: • NEVER centrifuge; GENTLY mix 5 x with complete inversions prior to testing. • A discard tube MUST be drawn, and CANNOT be an EDTA tube.
	Time requirements for sample testing: ☐ 10 MINUTES to 4 HOURS of collection time for PRUTest. ☐ 30 MINUTES to 4 HOURS of collection time for Aspirin.
	Reemphasize time to anti-coagulate and reiterate that samples with any evidence of clotting should not be used.
	Review biohazard guidelines: Universal precautions.

Running Quality Control (Refer to User Manual)	
	Perform EQC: review frequency; PASS vs. FAIL. Show section in the manual that discusses the parameters and their meaning.
	Perform WQC: Visually inspect pellet prior to use. Frequency recommendations: every new shipment/delivery or lot #. Additional PRUTest recommendation: every 30 days. Discuss outlier actions.
	Discuss and review internal QC channel in PRUTest and Aspirin cartridge.

Operator Training Checklist (Continued)

How to Run Sample (Refer to User Manual)	
	Open foil pouch immediately prior to test.
	Remove the needle cap by twisting clockwise until resistance is met, while continuing to twist clockwise, pull cap up. Do not put finger in the sample well.
	Read in Bar Code for Calibration Information if New Lot. (Run WQC if new lot).
	DO NOT remove the tube once it has been placed on the cartridge needle.
	DO NOT remove the cartridge and tube from the device until the test is completed.
	It is important to remove the cartridge after test is completed.

VerifyNow PRUTest (Refer to VerifyNow PRUTest package insert)	
	Perform VerifyNow PRUTest.
	Review P2Y12 Reaction Units (PRU).
	Review How to Enter Optional Baseline and calculate % inhibition.
	Review recall results.

VerifyNow Aspirin Test (Refer to VerifyNow Aspirin Test package insert)	
	Perform VerifyNow Aspirin Test.
	Review Aspirin Reaction Units (ARU).
	Review cutoff value (≥ 550 non-therapeutic).
	Review recall results.

Factors that can Affect a Test	
	Review effect of Glycoprotein IIb/IIIa inhibitors (ReoPro®, Integrilin, Aggrastat®).
	Point out that Hematocrit and Platelet limitations may be found in the package inserts.
	Misc. drugs that affect platelet function may be detected up to 14 days after ingestion. (e.g. refer to package insert for NSAIDS).
	Certain inherited platelet disorders (Glanzmann but not vWD) **will give an error code because the internal QC will fail.**
	Improper Sample Collection may produce an error code. Review proper sample collection once more – discard tube, Partial fill Greiner tube, 21 gauge needle, EDTA (purple top) drawn AFTER sample, avoid traumatic collections.

Operator Training Checklist (Continued)

Troubleshooting & Technical Support	
	Demonstrate contents and location of VerifyNow System User Manual and Package Inserts.
	Create an error: Press QC. Place a cartridge in the instrument. When the picture of a tube appears, remove the cartridge. An error 12 will appear. Look up the error in the User Manual and review the troubleshooting procedure.
	Review other error screens using the User Manual. Discuss the troubleshooting of attention messages 24 and 28 as part of this review.
	Review Cleaning Device: Use once every other week for preventive maintenance and for troubleshooting or when instructed by the instrument. Discard cleaning device after use. REMOVE STRIP. Stress this VERY IMPORTANT STEP. The instrument does not need to be on or in any particular test mode.
	Point out location of fan. Demonstrate removal of filter cover and filter cleaning (perform when necessary). Inspect filter biweekly when using cleaning cartridge. Replace fan filter yearly per preventative maintenance recommendations. NOTE: INSTRUMENT MUST BE OFF WHEN FAN FILTER REMOVED FOR INSPECTION OR CLEANING. USE NO TOOLS ON THE INSTRUMENT.
	Show location of fuse.
	Review instrument cleaning (Refer to User Manual): Wipe outside when contaminated and at least monthly per preventative maintenance recommendation.
	Point out Customer Support label.
	Printer (optional). Discuss printer setup and operation. Show troubleshooting steps – if printer error is suspected, shut down both instrument and printer, remove all connections and reconnect prior to startup.
	Provide an opportunity for any additional questions or discussion.

Operator/Trainee Signature: _____ Date: _____

Trainer Signature: _____ Date: _____

Sample Collection Training Checklist

Use this form to record the details of the training session. Make a copy for each person being trained. After completing a section, the trainee should read and initial the box next to each statement in that section. The trainer and trainee should both sign and date the checklist.

Facility: _____ Date: _____

Name of Operator/Trainee: _____

Trainer / Qualifications: _____

Products Trained:

☐ **Aspirin Test** ☐ **PRUTest**

Sample Collection & Handling (Refer to Package Insert)	
	Review tube types and requirements: Aspirin and PRUTest: Sodium Citrate Greiner Vacuette 2mL partial fill tubes. Discuss errors with inappropriate tubes.
	Review sample collection: 21 gauge or larger needle (i.e., 20 gauge); clean stick (platelet testing). **GENTLY** mix x5 complete inversions immediately upon collection. Use a discard tube. For Aspirin or PRUTest, the discard tube may be a blood culture, sodium citrate, or white top tube (or tube with no additive). It may **NOT** be a tube containing EDTA (purple top). • Store at room temperature. Do not freeze or refrigerate samples • Avoid hemolysis and contamination by tissue factors. • Do not test sample if there is any evidence of clotting. Redraw sample if there is evidence of a hemolysis in any other centrifuged tube that was collected at the same time.
	Pneumatic tube transport is not recommended.
	Emphasize handling and time requirements: NEVER centrifuge; GENTLY mix 5 x with complete inversions prior to testing. A discard tube MUST be drawn, and CANNOT be an EDTA tube.
	Time requirements for sample testing: • **10 MINUTES to 4 HOURS** after collection time for PRUTest. • **30 MINUTES to 4 HOURS** after collection time for Aspirin.
	Reemphasize time to anti-coagulate and reiterate that samples with any evidence of clotting should not be used.
	Review biohazard guidelines: Universal precautions.

Operator/Trainee Signature: _____ Date: _____

Trainer Signature: _____ Date: _____

Instrument Validation Studies

Overview

The following information represents the common procedures as specified by the Accrediting Organizations for initial validation of VerifyNow:

- **Trueness/Precision**
- **Method Correlation**
- **Instrument Correlation**
- **Reference Interval Studies**

Trueness (Precision) Study Protocol

Testing Method

Operators should be familiar with the technique required to manage the WQC material prior to performing this test.

1. **The process should be done across several days (i.e., 5 days) and by multiple operators to accommodate different techniques and environments.**
2. **The process is approved and determined by the Lab Medical Director and the Accreditation Organization, the process commonly involves testing Wet Quality Control material at 2 levels twice per day for a total of 10 results for each level.**
3. **The data collected can be analyzed by Accriva upon request. A template to be electronically sent must be completed entirely or will be returned for correction.**

Procedure

1. **Follow instructions for testing materials as outlined in the Quality Controls section of the VerifyNow User Manual and the VerifyNow Assay WQC Package Insert.**
2. **Record results as directed by policy.**
3. **Data analysis: the CV% for level 2 of WQC should not exceed 10%.**

Optional: Entering Data into the Template for Data Submission to Accriva

The template will be electronically sent to the requesting individual and has key sections in red that must be completed before any data analysis. Instructions for completing the template are included. Technical Support is available for data analysis of completed templates or any assistance:

- Email: **ilsd_techsupport@ilww.com**
- Technical Escalations Phone number: **1.800.579.2255**

Interpretation of Results: If the CV exceeds 10% repeat the testing after reviewing management of the WQC material and the correct operation of the VerifyNow Instrument.

Methods Correlation

Overview

Correlation is required if you are currently offering the assay using another system or method. The only technology that Accriva claims correlation to VerifyNow is optical platelet aggregometry. If you are currently offering aggregation studies using another technology, it may be necessary for you to perform correlation studies if you are going to substitute our technology for your current method(s), noting we do not claim correlation to technologies except the platelet aggregometer as discussed above.

- Email: **ilsd_techsupport@ilww.com**
- Technical Escalations Phone number: **1.800.579.2255**

Instrument Correlation

Overview

Acceptability criteria should be established by the Lab Medical Director.

Specifications in the PRUTest Instructions for Use (IFU) state acceptance criterion for between-instrument precision in whole blood samples as %CV ≤ 10%.

NOTE: In the clinical setting where the VerifyNow PRUTest is used, there are no acceptance criteria for between-day and total variation.

- Email: **ilsd_techsupport@ilww.com**
- Technical Escalations Phone number: **1.800.579.2255**

Reference Interval Studies (Normal Values Range)

Overview

The Reference Intervals may be established prior to using the new method to report patient results.

The Reference Interval study may be performed to determine the range for healthy individuals and this range would be included on the result reports.

CLSI Document C28-A3 states that as few as 20 individuals may be sufficient to verify a reference interval.

Recording Results on Templates from Accriva

The Reference Interval is required on all patient results by all regulatory agencies.

Each site may use the manufacturer's data as provided in the package insert or data from a text book or peer-reviewed journal provided the verification of this data is documented by performing the Reference Interval study in some form.

VerifyNow Reference Interval Studies (Normal Values Range) Protocol

Pre-evaluation

Prior to beginning the Reference Interval Study Protocol, review the following:

Each site may use the manufacturer's data as provided in the package insert or data from a text book or peer-reviewed journal provided the verification of this data is documented by performing the Reference Interval study in some form.

1. **Be familiar with all functions of the VerifyNow instrument and review the Operator's Manual.**
2. **Ensure the VerifyNow instrument has been fully validated and performing correctly by checking Quality markers such as EQC and WQC.**
3. **Read all package inserts.**
4. **Review this entire protocol before beginning the evaluation.**

Reference Interval Studies (Normal Values Range) (Continued)

Patient Population

1. A sufficient number of normal donor samples must be obtained.
2. CLSI Document C28-A3 states this evaluation may be completed using as few as 20 normal donors.

Procedure

1. Follow instructions for testing patient samples in the Package Insert.
2. Record results as directed by policy.

Quick Guide

Overview

Accriva does not have recommendations or requirements for validation of VerifyNow. The validation studies are approved and dictated by the Laboratory Medical Director based on the accrediting organization's requirements for implementing a new test/instrumentation. The VerifyNow Implementation Guide is available on our website, www.accriva.com, to help guide our customers with studies commonly performed for new implementations.

Aspirin Test is waived.
PRUTest is moderately complex.

Precision Study

Commonly conducted by running WQC, 2 levels twice per day over 5 days.

We have a Precision Study template to analyze data available from Technical Escalations, ilsd_techsupport@ilww.com.

Normal Reference Range Interval

Commonly conducted with 20 donors not exposed to antiplatelet medications, i.e., P2Y12 inhibitors (Plavix, Effient, Brilinta, or Ticlid), or customers may choose to verify and use the established reference range in the Instructions for Use (IFU).

Instrument Correlation

Commonly performed if 2 instruments are purchased.

Method Correlation

VerifyNow correlates only with LTA (Light Transmittance Aggregometry).

New customers can request a VerifyNow IQCP Template from Technical Escalations. The instrument serial number and account name with address is required to receive the template.

Support documents to help with the workload of implementing a new laboratory instrument and assays (e.g., CLSI formatted procedures, sample collection and handling instructions, and model lab reports) are available on our website at www.accriva.com.