Accumetrics, Inc. **FORM**	PART NO: 94027FM-1 REVISION: B Effective Date: JAN 30, 2013
TITLE: VerifyNow Training Checklist	Page 1 of 1

APPROVAL SIGNATURES

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Revision History

Revision	Summary of Change	C.O.#	Eff. Date
A	New form	8231	10/30/12
B	Change P2Y12 to PRUTest	8388	1/30/13

VerifyNow® System 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 last page.

Facility:	Date:
Name of Operator/Trainee:	Products Trained: ❑ Aspirin ❑ PRUTest ❑ IIb/IIIa
Trainer / Qualifications:	

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 ^{o}C or 36-77^{o}F for PRUTest and Aspirin; refrigerated at 2 to 8 ^{o}C or 36-46 ^{o}F for IIb/IIIa or 8 weeks at room temperature); keep in sealed foil pouch until ready to test.
	Sample tube needle (CAUTION: Never remove sample tube from test device!).
	Safety: DO NOT insert fingers or anything other than a test device, EQC, or sample tube into test device port or sample well.
	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.

Sample Collection and Handling (Refer to package insert)

	Review tube types and requirements: Greiner Vacuette 2 mL partial fill tubes; Lithium Heparin (3 mL) for IIb/IIIa (required for Integrilin®). 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. The discard may be a heparin tube only for the IIb/IIIa Test if the sample is to be tested on a heparin tube. 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. • **0 MINUTES to 15 MINUTES** of collection time for IIb/IIIa.
	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: new shipment/delivery or lot #; every 30 days for IIb/IIIa; recording; outlier actions. Visually inspect pellet prior to use.
	Discuss and review internal QC channel in PRUTest and Aspirin cartridge.

How to Run Sample (Refer to User Manual)

	Open foil pouch immediately prior to test.
	Remove needle cap by pulling straight up and immediately place in instrument. Do not twist and do not put finger in the sample well.
	Read in Bar Code for Calibration Information if New Lot. (Run wet QC 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 PRUTest).

VerifyNow Aspirin Test (Refer to VerifyNow Aspirin package insert)

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

VerifyNow IIb/IIIa Test (Refer to VerifyNow IIb/IIIa package insert)

	Perform VerifyNow IIb/IIIa Test.
	Review Platelet Aggregation Units (PAU).
	Review How to Enter Optional Baseline and calculate % inhibition.
	Review recall results.

VerifyNow® System

Training Checklist

Factors that Can Affect a Test

	Review effect of Gylcoprotein IIb/IIIa inhibitors (ReoPro®, Integrilin, Aggrastat®).
	Point out that Hematocrit and Platelet limitations may be found in the package inserts.
	Misc. drugs that affect PLT 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.

Troubleshooting and Technical Support (Refer to User Manual)

	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 use 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: