

VerifyNow[®]

System



Accriva
diagnostics

VerifyNow[®]
Reference Guide

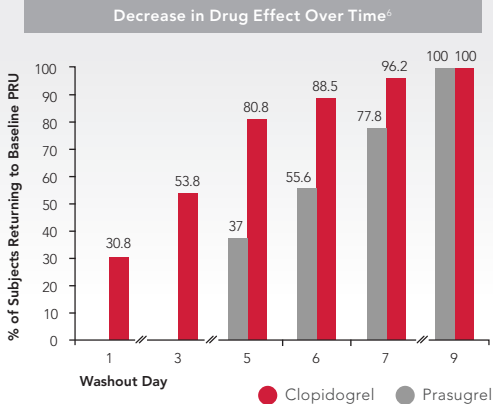
Interventional Procedure

Patients with inadequate response to their antiplatelet medications may be at significantly greater risk of myocardial infarction, stent thrombosis and death. Patients with hyper response to their antiplatelet medications may be at risk of bleeding.¹⁻³

Up to 40% of patients on antiplatelet medications may not receive the expected platelet inhibiting effect.⁴

Numerous factors may cause inadequate response,⁵ including:

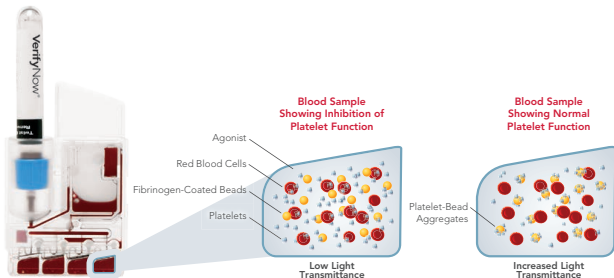
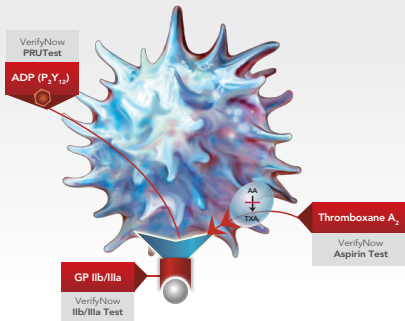
- Drug Interactions (e.g. proton pump inhibitors)
- Genetic differences
- Pre-existing health conditions (e.g. diabetes)
- Non-compliance



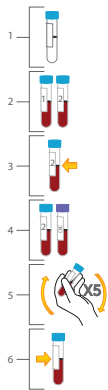
How It Works: Activates Specific Drug Receptor Sites

Receptor Blockade

- Measures the P2Y₁₂ platelet receptor blockade. Assesses patient response to antiplatelet therapy including clopidogrel (Plavix[®]), prasugrel (Effient[®]) and ticagrelor (Brilinta[®]).
- Measures the platelet response to aspirin by an arachidonic acid initiated reaction.
- Measures the patient response to IIb/IIIa inhibitors such as eptifibatid (Integrilin[®]) and abciximab (ReoPro[®]).



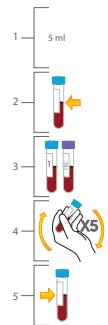
VerifyNow Aspirin or PRUtest Sample Collection Procedure*



Direct Venipuncture

Sample collection directly into vacuum collection tubes

1. Use 2 mL Greiner Bio-One partial-fill vacuette tubes with 3.2% sodium citrate (blue top). Greiner #454322.
2. Collect 2 tubes of whole blood using a 21 gauge or larger needle. First, collect a discard tube (at least 2 mL) making sure the discard tube does not contain any platelet inhibiting substance (e.g. EDTA). Butterfly (21 gauge) is OK to use.
3. Fill the second tube (sample tube) to the black line (1/2 tube). Do not under fill. Discard the first tube. Keep the second tube for testing.
4. If drawing blood for a CBC at the same time, fill the CBC tube last.
5. **Gently invert** the tube at least 5 times to ensure complete mixing of the contents. Samples with evidence of clotting should not be used. Do not shake, as that may give incorrect results.
6. Label the tube with the patient ID, date and time it was drawn. Do not refrigerate. Do not put in pneumatic tube system.



Indwelling Catheter

1. Discard the first 5 mL from an indwelling catheter to clear the line. Ensure the catheter is free of clots.
2. Immediately transfer blood to a 2 mL Greiner Bio-One partial-fill vacuette tube with 3.2% sodium citrate (blue top). Greiner #454322. Fill to the black line (1/2 tube). Do not under fill.
3. If drawing blood for a CBC at the same time, fill the CBC tube last.
4. **Gently invert** the tube at least 5 times to ensure complete mixing of the contents. Samples with evidence of clotting should not be used. Do not shake, as that may give incorrect results.
5. Label the tube with the patient ID, date and time it was drawn. Do not refrigerate. Do not put in pneumatic tube system.

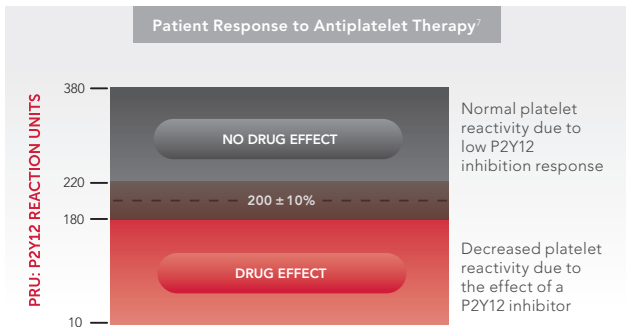
*Refer to the Instructions for Use for VerifyNow IIb/IIIa Test sample collection

VerifyNow PRUtest® Results: What is Reported?

The lab report may look similar to the following:

Patient Example PRUtest Results	Patient A	Units	Reference Range (off drug)
P2Y12 Reaction Units	132	PRU	180–376

Values less than 180 PRU suggest evidence of a P2Y12 inhibitor effect.



VerifyNow PRU Test Results

To Order This Test:

VerifyNow PRU Test:

Platelet response to P2Y₁₂ inhibitors (e.g clopidogrel, prasugrel, and ticagrelor).

PRU (P2Y₁₂ Reaction Units)

- ADP induced aggregation—extent of platelet aggregation in the presence of P2Y₁₂ inhibitors.
- Measures the On-Treatment Platelet Reactivity (OTPR) of ADP P2Y₁₂ receptor.

Pre-Surgical Application

- Studies show that there is patient variability in response to P2Y₁₂ inhibitors.⁸
- Patients that have been administered P2Y₁₂ inhibitors such as clopidogrel and prasugrel are at risk of perioperative bleeding due to platelet dysfunction from drug effect.
- It has been recommended to discontinue P2Y₁₂ inhibitors for 5 – 7 days prior to surgery⁹ for platelet function to be restored¹⁰, however, 2012 STS Guidelines¹¹ recommend using platelet function testing to aid in timing of surgery, instead of arbitrarily waiting a pre-specified period of time.

Conditions that May Affect Test Results

- Patient's exposure to GP IIb/IIIa inhibitors within 48 hours of eptifibatide (Integrilin[®]) or tirofiban (Aggrastat[®]), or 14 days of abciximab (ReoPro[®]).
- Improper sample collection.

VerifyNow Aspirin Test Results

To Order This Test:

VerifyNow Aspirin Test:

Platelet response to aspirin.

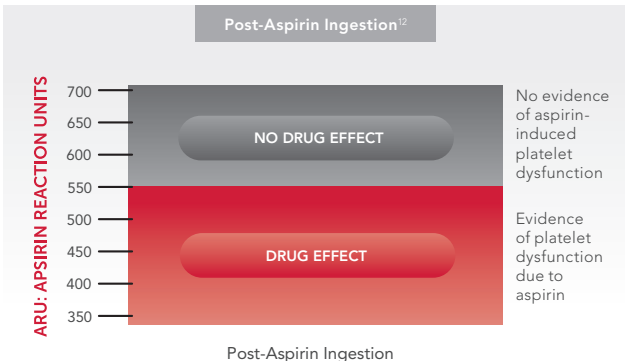
Result Interpretation:

≤ 549: Evidence of platelet dysfunction due to aspirin.

> 550: No evidence of aspirin-induced platelet dysfunction.

ARU (Aspirin Reaction Units)

Arachidonic acid induced aggregation.



VerifyNow IIb/IIIa Test Results

To Order This Test:

Platelet response to GP IIb/IIIa inhibitors, e.g. abciximab(ReoPro), eptifibatide(Integrilin).

PAU (Platelet Aggregation Units)

- Thrombin receptor induced platelet aggregation.

Reference Ranges

- | | |
|-----------------------------|-----------------------------|
| • abciximab: | • eptifibatide: |
| – Baseline: 125-330 PAU | – Baseline: 136-288 PAU |
| – >80% inhibition: 0-44 PAU | – >80% inhibition: 0-31 PAU |
| – >95% inhibition: 0-13 PAU | – >95% inhibition: 0-10 PAU |

% Inhibition

- Calculated by measuring pre-drug PAU and 10 minutes post start of IIb/IIIa inhibitor.

When to Test

- Prior to GP IIb/IIIa administration for baseline result (needed to calculate % inhibition).
- 10 minutes post GP IIb/IIIa administration for post drug result.
- If no baseline sample was collected, refer to abciximab and eptifibatide reference ranges.

Conditions that May Affect Test Results

- Test must be run within 15 minutes after drawing blood sample.
- Improper sample collection (platelet activation).

VerifyNow Test	Medication(s) Tested	Dose Given	Suggested Test Timing	Sample Incubation (Minutes)	Run Time (Minutes)
PRU _{Test}	Clopidogrel (Plavix [®])	75 mg	≥ 7 days on maintenance ¹	10	~ 3
		300 mg	≥ 8 hours post bolus ²		
		600 mg	≥ 6 hours post bolus ³		
	Prasugrel (Effient [®])	5 mg	≥ 5 days on maintenance ¹³		
		10 mg	≥ 5 days on maintenance ¹³		
		60 mg	≥ 45 minutes post bolus ⁸		
	Ticagrelor (Brilinta [®])	90 mg (bid)	≥ 1 day on maintenance ⁹ (within 8 hours of last dose for maximal effect)		
		180 mg	≥ 2 hours post bolus ⁹ (within 8 hours for maximal effect)		
Aspirin	Aspirin	0.25 mg/kg	≥ 2 hours post dose	30	~5
IIb/IIIa	Abciximab (ReoPro [®])	0.25 mg/kg	≤ 10 minutes post bolus ¹⁴	No incubation required (run within 15 minutes)	<2
	Eptifibatide (Integrilin [®])	180 mcg/kg	≤ 10 minutes post bolus ¹⁵		

Ordering Information

Catalog Number	Description
86000	VerifyNow Instrument System
85053	VerifyNow Aspirin Test, 25-Test Kit
85225	VerifyNow PRU Test, 25-Test Kit
85310	VerifyNow IIb/IIIa Test, 10-Test Kit
85047	VerifyNow WQC Kit
85062	VerifyNow Preventative Maintenance Kit

For more details, see the VerifyNow Test package insert.

1 Plavix [prescribing information]. Bridgewater, NJ: Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership; 2013. **2** Price, MJ et al. Am J Cardiol 2006;98:681-684. **3** Hochholzer W. et al. Circulation. 2005;111:2560-2564. **4** ADAPT DES. The Lancet, Volume 382, Issue 9892, Pages 614 - 623, August 17, 2013. **5** VerifyNow IIb/IIIa Test [package insert]. San Diego, CA: Accriva Diagnostics; 2016. **6** Price, MJ et al, J Am Coll Cardiol 2012;59:2338-43. **7** VerifyNow PRU Test [package insert]. San Diego, CA: Accriva Diagnostics; 2016. **8** Increased Active Metabolite Formation Explains the Greater Platelet Inhibition With Prasugrel Compared to High-dose Clopidogrel. June 26, 2007. **9** Husted S et al. Eur Heart J. 2006;27:1038-1047. **10** Brilinta [prescribing information]. Bridgewater, NJ: AstraZeneca group of companies; 2015. **11** 2012 Update to The Society of Thoracic Surgeons Guideline on Use of Antiplatelet Drugs in Patients having Cardiac and Noncardiac Operations. © 2012 by the Society of Thoracic Surgeons. Published by Elsevier Inc. **12** VerifyNow Aspirin Test [package insert]. San Diego, CA; Accumetrics; 2011. **13** Effient [prescribing information]. Indianapolis, IN: Daiichi Sankyo, Inc. and Lilly USA, LLC; 2015. **14** ReoPro IV [prescribing information]. Leiden, The Netherlands: Janssen Biologics B.V. and Eli Lilly and Company; 2013. **15** Integrilin IV [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; 2014.



6260 Sequence Drive | San Diego, CA 92121
858.263.2501 | customerservice@accriva.com
www.accriva.com