

VerifyNow[®]

System



Accriva
diagnostics

VerifyNow[®]
Reference Guide
For use outside the U.S. only

VerifyNow P2Y12 Test

Pre-surgical Application

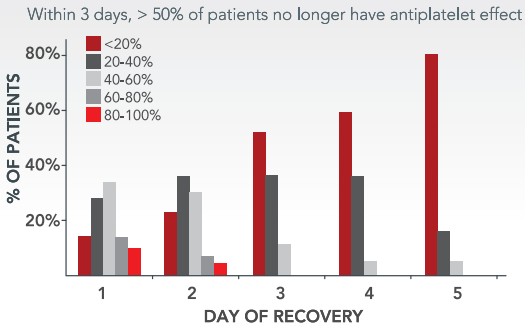
- Studies show that there is patient variability in response to P2Y12 inhibitors⁷.
- It has been recommended to discontinue P2Y12 inhibitors for 5 – 7 days prior to surgery⁸ for platelet function to be restored².
- 2012 STS Guidelines¹⁰ recommend using platelet reactivity testing to aid in timing of surgery, instead of arbitrarily waiting a pre-specified period of time (Class IIa level of evidence B).

Conditions that May Affect Test Results

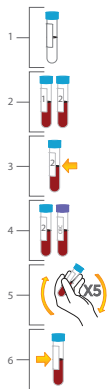
- Patient's exposure to GP IIb/IIIa inhibitors within:
 - 48 hours of eptifibatide
 - 14 days of abciximab
- Improper sample collection (platelet activation).

Clinical judgement is required for definition of high residual platelet reactivity and assessment of treatment strategies within your patient population.

DECREASE IN DRUG EFFECT OVER TIME¹



VerifyNow Aspirin or P2Y12 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.

VerifyNow P2Y12 Test

To Order This Test:

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

PRU (P2Y12 Reaction Units)

- ADP induced aggregation — extent of platelet aggregation in the presence of P2Y12 inhibitors.

Percent (%) P2Y12 Inhibition

- Estimation of percent change from baseline aggregation, and is calculated from the PRU result and the BASE result.

The lab report may look similar to the following:

Patient Example	Patient A	Units	Recommended Cutoff
P2Y12 Reaction Units	132	PRU	208
% P2Y12 Inhibition	58	%	16%

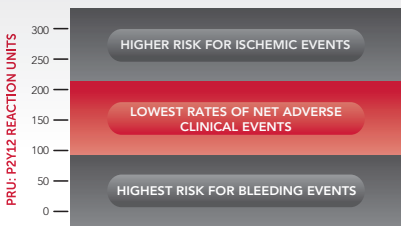
PRU \leq 208 represents specific evidence for the presence of a pharmacodynamic antiplatelet effect of a P2Y12 inhibitor.

PRU \leq 208 is associated with reduced rates of thrombosis and increased rates of bleeding due to the presence of the P2Y12 inhibitor effect.

PRU $<$ 95 is associated with the highest risk for major bleeding.

In P2Y12 inhibitor naive patients, the reference range for PRU is 194-418 and for percent inhibition is 0-16%.

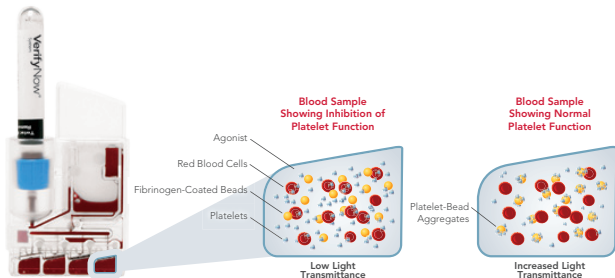
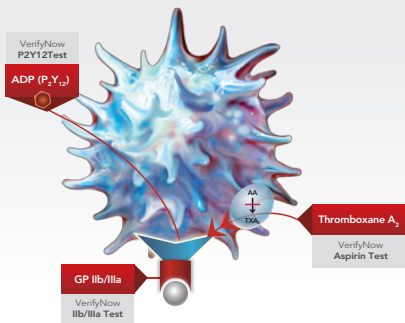
PRU RECOMMENDED CUTOFF¹⁵



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[®]), ticlopidine (Ticlid[®]), and ticagrelor (Brilinta/Brilique[™]).
- 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 IIb/IIIa Test

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:
 - Baseline: 125-330 PAU,
 - >80% inhibition: 0-44 PAU
 - >95% inhibition: 0-13 PAU
- eptifibatide:
 - Baseline: 136-288 PAU
 - >80% inhibition: 0-31 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 Aspirin Test

To Order This Test:

VerifyNow Aspirin Test

Platelet response to aspirin.

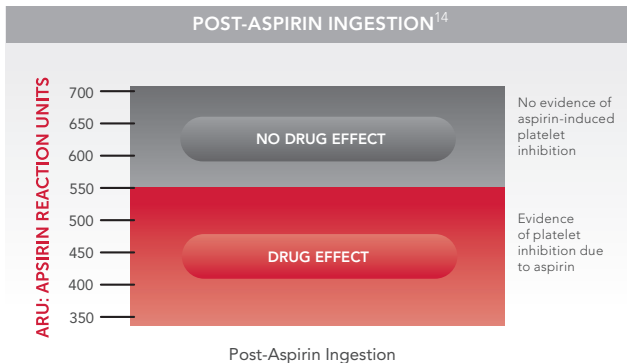
Result Interpretation

≤ 549 : Evidence of platelet inhibition due to aspirin.

≥ 550 : No evidence of aspirin-induced platelet inhibition.

ARU (Aspirin Reaction Units)

Arachidonic acid induced aggregation.



VerifyNow Test	Medication(s) Tested	Dose Given	Suggested Test Timing	Sample Incubation (Minutes)	Run Time (Minutes)
P2Y12 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		
	Ticagrelor (Brilinta/Brilique™)	90 mg (bid)	1 day on maintenance ⁷ (within 8 hours of last dose for maximal effect)		
		180 mg	2 hours post bolus ⁸ (within 8 hours for maximal effect)		
	Prasugrel (Effient®)	5 mg	5 days on maintenance ¹¹		
10 mg		5 days on maintenance ¹¹			
60 mg		45 minutes post bolus ⁹			
Ticlopidine (Ticlid®)	250mg	2 hours post dose ⁴			
	250mg (bid)	~21 days (steady rate) ⁴			
Aspirin	Aspirin	81–325 mg	2 hours post dose	30	~5

For more details, see the VerifyNow Test package insert.

1 Plavix (clopidogrel bisulfate) tablets Prescribing Information. Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership. 3/2010 Update. **2** Price, MJ et al. Am J Cardiol 2006;98:681-684. **3** Hochholzer W. et al. Circulation. 2005;111:2560-2564. **4** Ticlid (ticlopidine hydrochloride) tablets Prescribing Information. Roche Laboratories Inc. Revised 12/2005. **5** ADAPT DES. The Lancet, Volume 382, Issue 9892, Pages 614 - 623, August 17, 2013. **6** VerifyNow IIb/IIIa Test Package Insert. 14320.K. 2009-06-10. **7** Increased Active Metabolite Formation Explains the Greater Platelet Inhibition With Prasugrel Compared to High-dose Clopidogrel. June 26, 2007 **8** Husted S et al. Eur Heart J. 2006;27:1038-1047 **9** Brilinta (ticagrelor) tablets prescribing information. AstraZeneca group of companies. July 20, 2011. **10** 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. **11** Breet, NJ. et al. J Thromb Haemost 2010 Oct;8(10):2140-8. **12** Breet, NJ. et al. Heart 2011 Jun;97(12):983-90. **13** Jimenez, AH. et al. Am J Cardiol. **14** VerifyNow Aspirin Test [package insert]. San Diego, CA; Accumetrics®; Revised April 2011. **15** VerifyNow P2Y12 Test [package insert]. San Diego, CA; Accumetrics®; Revised April 2011.

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