VerifyNow P2Y12 Test

Pre-surgical Application

- Studies show that there is patient variability in response to P2Y12 inhibitors\(^7\).
- It has been recommended to discontinue P2Y12 inhibitors for 5 – 7 days prior to surgery\(^8\) for platelet function to be restored\(^2\).
- 2012 STS Guidelines\(^10\) 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 TIME\(^1\)

Within 3 days, > 50% of patients no longer have antiplatelet effect
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

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:

<table>
<thead>
<tr>
<th>Patient Example</th>
<th>Patient A</th>
<th>Units</th>
<th>Recommended Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2Y12 Reaction Units</td>
<td>132</td>
<td>PRU</td>
<td>208</td>
</tr>
<tr>
<td>% P2Y12 Inhibition</td>
<td>58</td>
<td>%</td>
<td>16%</td>
</tr>
</tbody>
</table>

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

**PRU ≤ 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%.
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 eptifibatide (Integrilin®) and abciximab (ReoPro®).

![Diagram showing how it works](image)
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
Platelet response to aspirin.

Result Interpretation
\( \leq 549 \): Evidence of platelet inhibition due to aspirin.
\( \geq 550 \): No evidence of aspirin-induced platelet inhibition.

ARU (Aspirin Reaction Units)
Arachidonic acid induced aggregation.

![Diagram of POST-ASPIRIN INGESTION](image)

- **No evidence of aspirin-induced platelet inhibition**
- **Evidence of platelet inhibition due to aspirin**

Post-Aspirin Ingestion

To Order This Test:
<table>
<thead>
<tr>
<th>VerifyNow Test</th>
<th>Medication(s) Tested</th>
<th>Dose Given</th>
<th>Suggested Test Timing</th>
<th>Sample Incubation (Minutes)</th>
<th>Run Time (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2Y12 Test</td>
<td>Clopidogrel (Plavix®)</td>
<td>75 mg</td>
<td>7 days on maintenance¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>300 mg</td>
<td>8 hours post bolus²</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>600 mg</td>
<td>6 hours post bolus³</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ticagrelor (Brilinta/Brilique™)</td>
<td>90 mg (bid)</td>
<td>1 day on maintenance⁷ (within 8 hours of last dose for maximal effect)</td>
<td>10</td>
<td>~3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>180 mg</td>
<td>2 hours post bolus⁸ (within 8 hours for maximal effect)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prasugrel (Effient®)</td>
<td>5 mg</td>
<td>5 days on maintenance¹¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg</td>
<td>5 days on maintenance¹¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>60 mg</td>
<td>45 minutes post bolus⁹</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Ticlopidine (Ticlid®)</td>
<td>250 mg</td>
<td>2 hours post dose⁴</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>250 mg (bid)</td>
<td>~21 days (steady rate)⁴</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aspirin</td>
<td>81–325 mg</td>
<td>2 hours post dose</td>
<td>30</td>
<td>~5</td>
</tr>
</tbody>
</table>

For more details, see the VerifyNow Test package insert.