VerifyNow®
System

Accriva diagnostics
VerifyNow®
Reference Guide
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.\textsuperscript{1-4}

Up to 40\% of patients on antiplatelet medications may not receive the expected platelet inhibiting effect.\textsuperscript{5}

**Numerous factors may cause inadequate response,\textsuperscript{6} including:**

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

**Decrease in Drug Effect Over Time\textsuperscript{14}**

<table>
<thead>
<tr>
<th>Washout Day</th>
<th>% of Subjects Returning to Baseline PRU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30.8</td>
</tr>
<tr>
<td>3</td>
<td>53.8</td>
</tr>
<tr>
<td>5</td>
<td>37</td>
</tr>
<tr>
<td>6</td>
<td>55.6</td>
</tr>
<tr>
<td>7</td>
<td>77.8</td>
</tr>
<tr>
<td>9</td>
<td>100</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Clopidogrel  \textsuperscript{14} Prasugrel
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 194–418

Values less than 194 PRU are specific evidence of a P2Y12 inhibitor effect.
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\(^7\).
- 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 surgery\(^8\) for platelet function to be restored\(^9\), however, 2012 STS Guidelines\(^10\) 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\(^\text{®}\)) or tirofiban (Aggrastat\(^\text{®}\)), or 14 days of abciximab (ReoPro\(^\text{®}\)).
- Improper sample collection.
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.

To Order This Test:
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 eptifibatide (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.
<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>PRU Test</td>
<td>Clopidogrel (Plavix®)</td>
<td>75 mg</td>
<td>≥ 7 days on maintenance&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
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<td></td>
<td></td>
<td>300 mg</td>
<td>≥ 8 hours post bolus&lt;sup&gt;2&lt;/sup&gt;</td>
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<tr>
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<td></td>
<td>600 mg</td>
<td>≥ 6 hours post bolus&lt;sup&gt;3&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>Prasugrel (Effient®)</td>
<td>5 mg</td>
<td>≥ 5 days on maintenance&lt;sup&gt;11&lt;/sup&gt;</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg</td>
<td>≥ 5 days on maintenance&lt;sup&gt;11&lt;/sup&gt;</td>
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<tr>
<td></td>
<td></td>
<td>60 mg</td>
<td>≥ 45 minutes post bolus&lt;sup&gt;9&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>Ticagrelor (Brilinta®)</td>
<td>90 mg (bid)</td>
<td>≥ 1 day on maintenance&lt;sup&gt;7&lt;/sup&gt; (within 8 hours of last dose for maximal effect)</td>
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<tr>
<td></td>
<td></td>
<td>180 mg</td>
<td>≥ 2 hours post bolus&lt;sup&gt;8&lt;/sup&gt; (within 8 hours for maximal effect)</td>
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<tr>
<td></td>
<td>Aspirin</td>
<td>81–325 mg</td>
<td>≥ 2 hours post dose</td>
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<td>30</td>
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</table>

For more details, see the VerifyNow Test package insert.