

WELCOME

Welcome to the first edition of the Accumetrics Technical Bulletin.

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QUESTIONS:

Please call:
+1(858) 643 1640
Or mail to:
support@accumetrics.com

Your VerifyNow® System Can Measure the Effect of Effient™ (Prasugrel), the New Generation of Antiplatelet Medication

Recently the FDA approved Effient™ (prasugrel) as an antiplatelet agent in certain patients with acute coronary syndrome who are managed with percutaneous coronary intervention (PCI). Effient is the third in the class of drugs known as thienopyridines that include Ticlid® (ticlopidine), approved in 1991, and Plavix® (clopidogrel) approved in 1997. Thienopyridines affect platelet function by binding to the P2Y12 receptor and inhibiting ADP-induced aggregation. Detailed information concerning the indications for use of Effient can be found at www.effient.com. (Continued on Pg 2)



PROFICIENCY TESTING MATERIALS ARE NOW AVAILABLE!

Proficiency materials for 2010 may be ordered from the College of American Pathologists (CAP). The product to purchase for the Accumetrics assays is **Platelet-Induced Aggregation (PIA)** described on page 129 of the 2010 Surveys Catalog. Additional information may be obtained by calling the CAP at (800) 323-4040 option 1 or at www.cap.org. φ



How to Reset Your Instrument Clock

It's that time of year again and as we "fall back" it is also necessary to reset the clock in your VerifyNow instrument. Just follow the steps below to perform this simple procedure:

1. Press the soft key beside the wrench on the Main Screen to access the maintenance menu.
2. Press the soft key beside the forward arrow (top icon) twice.
3. Press the soft key beside the big clock (second icon).
4. The cursor should be in the "hour" field. Set the hour using the numerical keypad at the bottom. Remember that the VerifyNow instrument uses a 24 hour clock.
5. You can also reset the minute by pressing the *Tab* button to place the cursor in the "minutes" field.
6. Likewise, you can continue to press *Tab* as you need to reset the day, month or year.
7. Remember that no changes will take effect until you press the soft key beside the "Save" button indicated by the computer diskette. Press this key to save your new time.
8. Press the back button (bottom icon) at the bottom of the screen to return to the Main Screen. φ



Your VerifyNow® System can Measure the Effect of Effient™ (Prasugrel) - Continued from Pg 1

We often get questions about the naming of our P2Y12 test. When the test was first cleared by the FDA in 2005, it was available for use to measure platelet inhibition by the two P2Y12 inhibitors approved at that time (Plavix and Ticlid). However, we knew that the P2Y12 platelet receptor was the target of other drugs in development, so chose to name the test to reflect the fact that it measured receptor activity independent of the inhibitor used.

Your physicians may begin to use Effient, and question if your laboratory can measure the level of platelet inhibition of Effient as well as Plavix. Our P2Y12 test measures the extent of inhibition of the P2Y12 receptor by all approved thienopyridines. This means that the test can be used to measure the level of platelet inhibition caused by Plavix (clopidogrel), Ticlid (ticlopidine), and the recently approved Effient (prasugrel). Please note that studies have shown that the resulting inhibition of platelets by Effient therapy may be significantly greater than Plavix, so you can expect to see PRU and percent inhibition results that indicate a significantly increased level of inhibition in patients on Effient.

Many of you currently refer to the P2Y12 test as the Plavix test in your laboratory information system and test ordering information. You may wish to take this opportunity to rename the test (e.g. P2Y12 test) to reflect its ability to measure platelet inhibition by all thienopyridines that inhibit the P2Y12 receptor. φ

Introducing Accumetrics' New Instrument Maintenance/Warranty Program

The VerifyNow Extended Service Agreements ensure continued reliability and performance beyond the first year warranty. Under these Agreements, Accumetrics offers service and support for the System in one-, two-, and three-year options that provide:

- **System repair or replacement within 2 business days of notification**
- **Service to include shipping, labor, diagnosis and repair or replacement, as necessary**
- **Software and hardware updates during covered period**
- **Annual preventive maintenance kit provided at the beginning of each service contract year**

**For more information, contact
Accumetrics Customer Support
at (800) 643-1640 | (858) 643-1600**



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CLINICAL SCIENCE CORNER

From the American Heart Journal:

Assessment of P2Y12 inhibition with the point-of-care device VerifyNow P2Y12 in patients treated with prasugrel or clopidogrel coadministered with aspirin.

Varenhorst C. et al. Am Heart J 2009;157:562.e1-562.e9.

Prasugrel (Effient™) is a third generation thienopyridine developed by Eli Lilly that recently received approval from the FDA. Like clopidogrel (Plavix®), Effient must be metabolized in the liver to produce the active form that binds to the ADP-initiated P2Y12 receptor. Clinical trials show that the level of platelet inhibition by Effient is significantly greater than that of Plavix, possibly because the production of the active metabolite of Effient by the liver involves fewer steps requiring cytochrome activity in the liver.

The clinical trials for the efficacy and safety of prasugrel include TRITON TIMI-38 and PRINCIPLE TIMI-44. The TIMI-38 trial compared prasugrel to the FDA approved dose of clopidogrel consisting of a 300 mg bolus followed by a maintenance dose of 75 mg daily. The TIMI-44 trial compared prasugrel to the often practiced use of a 600 mg bolus of clopidogrel followed by a maintenance dose of 75 mg a day. The conclusion of both trials is that prasugrel imparts a significantly increased level of platelet inhibition, but also increases the risk of major bleeding.

The VerifyNow Test was incorporated into substudies of the effect of prasugrel. This recent publication supports the use of the Accumetrics VerifyNow P2Y12 Test to monitor both clopidogrel and prasugrel. The VerifyNow P2Y12 Test was shown to correlate strongly with the light transmission aggregometry, as well as the flow cytometric VASP assay. The VerifyNow P2Y12 results also correlated to exposure of the active metabolite of both prasugrel and clopidogrel, as determined by measurement of the active metabolite concentration in the sample. Additionally, the publication shows a strong agreement between the percent inhibition reported by the test using the baseline channel containing thrombin receptor activating peptides, and the percent inhibition obtained by measuring a subject before and after exposure to either drug. φ