DIAGNOSTIC LABORATORY SERVICES, INC.

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Technical Bulletin

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Introducing Platelet Function Assay (PFA-100) and Discontinuation of Bleeding Time.

Diagnostic Laboratory Services is pleased to announce the introduction of a new test that evaluates platelet function, the PFA-100. This system is a high shear flow system that measures platelet adhesion and aggregation in-vitro from citrated whole blood. The PFA-100 test induces platelet activation as blood flows through an aperture cut into a membrane that is coated with collagen and epinephrine or collagen and ADP. The time taken for a platelet plug to form, resulting in aperture closure, is referred to as the Closure Time (CT) and is reflective of platelet function. The test shows good reproducibility and specificity to platelet dysfunction disorders.

It is well-documented in the literature that the Bleeding time (BT) is not a useful predictor of risk of hemorrhage associated with surgical procedures and a normal bleeding time does not exclude the possibility of excessive hemorrhage associated with invasive procedures. BTs also suffer from significant subjectivity when interpreting results depending on who performed the test, variability in test results depending on incision location, skin, soft tissue, or vascular irregularities that adversely contribute to the overall result, and significant patient discomfort and stress. In addition, recent regulatory changes have restricted the location and personnel able to perform the test.

Beginning April 12, 2010, DLS will be performing testing on the PFA-100 system on Oahu. DLS will completely discontinue the performance of BTs for all of its locations. If you have any questions regarding platelet function testing for locations other than Oahu, please call:
Dr. Wesley Kim (589-5131), Dr. Ana Ortega-Lopez (547-4271) or DLS Client Services (589-5101).

When interpreting PFA-100 results, abnormally prolonged CTs may be seen in patients with von-Willebrand disease (vWD), various congenital platelet defects (storage pool and/or release defects), or exposure to aspirin or aspirin containing medications (Table 1). In some cases, additional follow-up confirmatory testing may be required (i.e vWD panel or formal platelet aggremometry). PFA-100 results may also be a helpful tool to aid in the therapeutic monitoring of patients with vWD.

Table 1. Expected patterns of PFA-100 CTs

Test cartridge	**Normal**	**Aspirin**	**Von Willebrands Disease**	**Glanzmann's thrombasthenia**
Col/EPI	Normal	Abnormal	Abnormal	Abnormal
Col/ADP		Normal	Abnormal	Abnormal

The PFA-100 is not designed to predict bleeding during surgical procedures. In fact, the best screening test for this is a detailed clinical history that includes family, surgical and drug history. However, in the presence or absence of clinical history suggestive of a bleeding disorder, the PFA-100 can be used to decide whether a patient has evidence of vWD or a significant platelet adhesion or aggregation problem which may place them at higher risk of bleeding and allows for better overall patient management.

There are a number of anti-platelet agents on the market and in use, including the Thienopyridines (Ticlopidine, Clopidogrel) and GPIIb/IIIa inhibitors (ReoPro, Aggrastat, Integrilin). While there are some documented smaller studies in the literature showing the correlation between these drugs and PFA-100 CTs, there is no formal consensus or guidelines in regards to the effect of these drugs on PFA-100 CT results or the use of the PFA-100 test in patients on these drugs. In addition, there are situations where abnormally prolonged CTs on the PFA-100 test can result when the patient's platelet count is below

100,000 or their hematocrit is < 35%, even in the absence of true platelet dysfunction. As such, in all cases, correlation of the PFA-100 result with the clinical and drug history is very important.

Test	Order Code	CPT Code	List Price
Platelet Function Assay	4125	85576	$60.00

If you have any additional questions please feel free to contact:
Dr. Wesley Kim (589-5131), Dr. Ana Ortega-Lopez (547-4271) or DLS Client Services (589-5101).

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