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Improved Turnaround Time for Platelet Factor 4 Assay in Assessing Patients with Possible Heparin-induced Thrombocytopenia

Effective June 3, 2021, the platelet factor 4 (PF4) immunoassay used in diagnosing heparin-induced thrombocytopenia (HIT) will become available two times per day on weekdays and generally once per day on weekends/holidays. Testing will be performed on the ACL TOP instrument in the 24-hour laboratory. This improved turn-around-time (TAT) can assist in evaluating these often complicated patients with thrombocytopenia and increased risk for thrombotic events. Emergent testing during off hours can be arranged by contacting a clinical pathologist via cell

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Additional availability for platelet factor 4 immunoassay:

References:

- 1. Warkentin T. Combination of two complementary automated rapid assays for diagnosis of heparin-induced thrombocytopenia (HIT). 2020. *J Thromb Haemost*, 18; 1435-1146.
- 2. Greinacher A. Heparin-Induced Thrombocytopenia. 2015. *N Eng J Med*, 373: 252-261.

Heparin (both unfractionated and low molecular weight) continues to be widely used in clinical practice due to its easy reversibility and low cost. A rare complication, however, is HIT which requires discontinuation of all heparin and switching to alternative anticoagulation; e.g. bivalirudin. The "4T" scoring system should be used to assess the pre-test probability of HIT. The PF4 assay is highly sensitive with fairly good specificity (especially with strongly positive results). Thus, a negative result essentially excludes HIT; in rare circumstances repeat testing may be appropriate. A positive result will trigger reflex confirmatory testing by the serotonin release assay (SRA) performed by Versiti (formally Blood Center of Wisconsin) with about 2-3 day TAT; in the meantime, switching to alternative anticoagulation is usually appropriate.

This test is FDA approved for qualitative result reporting: either positive or negative. If the optical density value is requested, please contact a clinical pathologist or technical specialist. The ACL TOP assay is a combined IgG/IgM method and may have slightly less specificity than the current Immunocor IgG assay. However, as a negative rule-out strategy, this is not a significant concern. Historically 95% of tests have been negative.

Testing will not be performed if the platelet count exceeds 150 K/uL. Testing will be paused and the sample will be held for 5 days, after which testing will be cancelled and credited. Testing of patients without thrombocytopenia requires laboratory approval.

For additional information, please contact Marshfield Labs Customer Service (1-800-222-5835) and direct any questions to Jill Brantner, Dr. Gene Shaw, or Dr. Kajal Sitwala.