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**Lab Dept:** Serology

**Test Name:** HEPARIN-PF4 ANTIBODY (HIT), SERUM

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***General Information***

**Lab Order Codes:** HITS

**Synonyms:** Heparin Induced Antibody; Heparin-Dependent Antibody; HIT; PF4

**CPT Codes:** 86022 – Antibody ID, platelet antibodies

**Test Includes:** Heparin P4 Antibody level reported as Elisa Optical Density (OD), Heparin Inhibition (%) and Interpretation.

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***Logistics***

**Test Indications:** Useful for detection of IgG antibodies directed against heparin/platelet factor 4 complexes that are implicated in the pathogenesis of immune-mediated type II heparin induced thrombocytopenia (HIT-II).

Clinical picture of HIT type II:

- Patients not previously exposed to heparin
- Decrease in platelet count (thrombocytopenia) of 50% or more from baseline or postoperative peak.
- Onset of thrombocytopenia beginning approximately 5-10 days after initiation of heparin. This may or may not be associated with new or progressive thrombosis in patients treated with heparin.

Patients previously exposed to heparin (especially within the preceding 100 days), in addition to the above findings, the onset of thrombocytopenia could occur with 24-48 hours after reexposure to heparin.

**Lab Testing Sections:** Serology - Sendouts

**Referred to:** Mayo Medical Laboratory (MML Test: HITIG)

**Phone Numbers:** MIN Lab: 612-813-6280

STP Lab: 651-220-6550

**Test Availability:** Daily, 24 hours

**Turnaround Time:** 1 – 3 days

**Special Instructions:** Serum gel tubes are not acceptable

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***Specimen***

**Specimen Type:** Blood

**Container:** Red top NO GEL tube

**Draw Volume:** 3 mL (Minimum: 1.5 mL) blood

**Processed Volume:** 1 mL (Minimum: 0.5 mL) serum

**Collection:** Routine venipuncture

**Special Processing:** Lab Staff: Centrifuge specimen. Remove serum aliquot into a screw-capped plastic vial. Store and ship at frozen temperatures. Forward promptly.

**Patient Preparation:** None

**Sample Rejection:** Warm specimens, unlabeled or mislabeled specimens; gross hemolysis; gross lipemia; specimens collected in gel tubes

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***Interpretive***

**Reference Range:**

Results are reported as: 1) Heparin-induced thrombocytopenia (HIT) ELISA Optical Density (OD); 2) Heparin inhibition (%); 3) Interpretation. Typical patterns of results and interpretations are depicted in the following table. Interpretive comments will also accompany test reports when indicated.			
Result Field	HIT ELISA OD	Heparin Inhibition (%)	Interpretation
Normal Range	<0.400 OD	Not done	Negative
Positive	>or =0.400 OD	> or =50%	Positive
Equivocal	>or =0.400 OD	<50%	Equivocal

A negative result of testing for H/PF4 antibodies has about 90% negative predictive value for exclusion of clinical Type II (HIT-II).

Because up to 10% of patients with HIT may have a negative H/PF4 ELISA result, a negative H/PF4 antibody ELISA result does not exclude the diagnosis of HIT when clinical suspicion remains high. A functional assay for HIT antibodies (eg, HDPA or SRA) may be helpful in these circumstances.

A positive result is indicative of the presence of H/PF4 complex antibodies. However, this test's specificity is as low as 20-50% for clinical diagnosis of HIT, depending on the patient population studied. For example, up to 50% of surgical patients and up to 20% of medical patients treated with heparin may develop H/PF4 antibodies as measured by ELISA, and only a small proportion (1-5%) develop clinical HIT. Accordingly, this test does not confirm the diagnosis of Type II HIT. The diagnosis must be made in conjunction with clinical findings, including evaluation for other potential causes of thrombocytopenia.

The presence of H/PF4 antibodies likely increases the risk of clinical HIT, with risk probably partly dependent on associated medical and surgical conditions, but currently there are few data about relative risk of HIT in various populations with positive tests for H/PF4 antibodies.

**Critical Values:**

N/A

**Limitations:**

HIT is a clinical diagnosis that is complimented by laboratory testing for HDPA antibodies and/or antibodies to H/PF4 complexes. Assay results provide information on the presence or absence of H/PF4 antibodies which are implicated in the pathogenesis of the HIT-II with or without thrombosis. However, results of the H/PF4 antibody assay must be interpreted in conjunction with clinical findings and other pertinent tests to evaluate other causes of thrombocytopenia (eg, sepsis, intravascular coagulation, and fibrinolysis, thrombotic thrombocytopenia purpura, post-transfusion purpura, malignancy, drug-induced thrombocytopenia, autoimmune thrombocytopenia) or to confirm the findings of this assay.

Some low titer, low avidity antibodies and some antibodies that recognize sites on H/PF4 complex may not be detected using this assay.

Some patients may have naturally occurring antibodies for PF4 (no evidence of heparin dependence) of no known significance with respect to pathogenesis of HIT-II.

**Methodology:**

Enzyme-Linked Immunosorbent Assay (ELISA)

**References:**

[Mayo Medical Laboratory Web Page](#) May 2017