



New Assay for Heparin-Induced Thrombocytopenia

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We are pleased to announce the availability of an immunologic assay for identification of antibodies against platelet factor 4-heparin complexes, which are associated with heparin-induced thrombocytopenia (HIT). This assay will replace the currently available functional HIT assay in most clinical settings.

Antibody mediated heparin-induced thrombocytopenia occurs in approximately 2%-4% of patients receiving unfractionated heparin (UFH) therapy, less commonly in patients receiving low molecular weight heparin (LMWH). Although most patients will have complete recovery with discontinuation of heparin therapy, approximately 25% of patients with HIT will develop thrombotic complications. Identifying HIT quickly and correctly is important in stopping heparin and initiating appropriate alternative therapy (at this time Argatroban and recombinant hirudin are approved for HIT).

Tests for HIT are either immunologic or functional. The immunologic assays identify antibodies directed against heparin-platelet factor 4 (PF4) complexes, which are usually the antibodies which cause HIT. This assay will be positive in greater than 90% of patients with HIT. A small percentage of patients will have antibodies directed against other antigens. The immunologic HIT test is therefore very sensitive. This sensitivity comes with a decreased specificity; up to 40% of cardiac bypass patients will have positive tests despite having no clinical findings of HIT. Functional tests may supplement positive immunologic testing in settings of high (clinical) false positives.

HIT should be suspected clinically when the platelet count falls by greater than 50% (it may still be within the normal range) about 5-10 days after exposure to heparin (or LMWH). In some cases thrombocytopenia may occur immediately after exposure if the patient has received heparin in the previous 100 days. The highest risk of HIT is in postoperative patients receiving prophylactic unfractionated heparin for more than 5 days. Medical patients receiving LMWH prophylaxis have among the lowest risks. Because of the frequency and potentially devastating effects of HIT in highest-risk patients, platelet levels should be evaluated at least every other day from day 4 to day 10. In intermediate level risk, monitoring of platelets should be performed 2 or 3 times from days 4 to 10, while monitoring is unnecessary in low-risk patients.

High risk for HIT	Post-operative patients receiving prophylactic or therapeutic UFH	After baseline platelet count, check platelets every other day of days 4-10 of UFH therapy.
Intermediate risk for HIT	Medical or obstetrical patients receiving prophylactic or therapeutic UFH, post-operative patients receiving prophylactic LMWH	After baseline platelet count, check platelets 2 or 3 times during days 4-10 of UFH therapy.
Low risk for HIT	Medical or obstetrical patients receiving prophylactic or therapeutic LMWH	No monitoring recommended.

If a patient has received heparin within 100 days of re-exposure, a repeat platelet level obtained within 24 hours of re-instituting heparin should be compared to a baseline value.

If a thrombotic event occurs while the patient is on heparin therapy, a platelet count should be obtained and compared to recent values.

Quick Facts

- ▶ Heparin-induced thrombocytopenia remains common.
- ▶ HIT should be suspected for those who develop thrombocytopenia or thrombosis after exposure to heparin.
- ▶ Immunologic assays (ELISAs) have improved sensitivity and will be the appropriate first test.
- ▶ Functional assays are still available to help evaluate potential false-positive immunologic studies.

For more information, please contact Client Services or see us on the Web at



When HIT is suspected by clinical findings, a HIT test should be ordered, and the immunologic assay will be performed. If a negative result is obtained in a clinical setting that still strongly suggests HIT, a functional test may be positive when the ELISA (immunologic assay) is negative or a repeat immunologic assay after 1-2 days may be positive. In some clinical setting, for example, post-cardiac bypass where the immunologic assays are frequently positive without evidence of HIT, positive immunologic tests may be evaluated by a follow up functional study.

Test Information

DESCRIPTION **HIT ANTIBODY**

METHOD EIA

ORDER CODE HITA

CPT CODE 86022

SPECIMEN 1 mL frozen buffered sodium citrate plasma (blue-top tube). Spin 10 minutes in refrigerated centrifuge at 3000 rpm. Separate into a plastic tube and re-spin. Separate into 2 plastic tubes and freeze at -70°C (critical frozen). Store and transport frozen. Separate samples must be submitted when multiple tests are ordered.

COMMENTS *Minimum amount:* 0.5 mL. Blood/anticoagulant volume is critical.
Unacceptable conditions: hemolyzed, short sample considerably below 9:1 ratio, and clotted samples.
Stability: 24 hours at room temperature, 24 hours refrigerated, 6 months frozen.

SCHEDULE Monday – Saturday

TURNAROUND 24 hours

RANGES **Heparin-Induced Thrombocytopenia Antibody** Negative

Interpretation:

Negative Immunoassays for heparin antibodies are considered sensitive (GT 90%); however, false-negatives can occur. If clinically indicated, repeat testing with a new sample in several days is suggested. When negative immunoassays occur within a strong clinical setting, functional testing for HIT may be indicated.

Positive Immunoassays for heparin antibodies are considered sensitive (GT 90%); however, the presence of antibody alone does not determine clinical heparin-induced thrombocytopenia. Results of this assay should be used in conjunction with clinical findings and to assess management.

Equivocal If clinically indicated, repeat immunoassay testing for heparin antibodies with a new sample in several days is suggested.

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