

July 27, 2009

MEMO

TO: Customers

FROM: Betsy Vokac
Marketing Manager, Diagnostic Laboratories

Blood Services
Medical Services
Diagnostic Laboratories
Blood Research Institute

RE: Improved Test for Detection of Heparin Dependent Platelet Antibodies

BloodCenter of Wisconsin is replacing its platelet factor 4 ELISA (PF4 ELISA) for detection of heparin dependent platelet antibodies. The new method detects only IgG antibodies. Importantly, it is as sensitive but more specific than the test it replaces, which simultaneously detected IgG, IgA and IgM antibodies (PF4 ELISA-IgGAM). A strong positive result in the new test correlates well with the clinical likelihood of heparin-induced thrombocytopenia (HIT).

The new Heparin Dependent Platelet Antibody - PF4 ELISA -IgG is a sensitive and specific assay for HIT antibodies in patients with a reasonable likelihood of having HIT based on clinical findings. The test will detect clinically significant IgG HIT antibodies, while avoiding detection of more non-clinically significant antibodies compared to the PF4 ELISA-IgGAM.

Although IgG heparin dependent platelet reactive antibodies are responsible for most HIT cases, patients may develop IgM or IgA antibodies in the absence of IgG that are clinically relevant. Such patients would be expected to exhibit compelling clinical features of HIT in the absence of a positive PF4 ELISA-IgG or platelet activation assay (e.g. Serotonin Release Assay). In order to detect and identify these unusual antibodies, we are introducing isotype specific IgM and IgA PF4 ELISAs that are more sensitive and more specific for these non-IgG antibodies than the previously available PF4 ELISA-IgGAM.

We now offer an expanded, comprehensive group of assays for HIT antibody detection. These include the highly sensitive and specific Serotonin Release Assay (SRA), the PF4 ELISA-IgG and PF4 ELISAs for individual IgA and IgM antibody isotypes. All of the PF4 ELISAs include a heparin inhibition step which further improves assay specificity.

| LABORATORY TEST | APPLICATION |
|-------------------------------------|---|
| PF4 ELISA - IgG | First line test when HIT is suspected |
| Serotonin Release Assay (SRA) | Confirms weak results obtained from a PF4 ELISA-IgG or a PF4 ELISA -IgGAM Detects antibodies that cross-react with low molecular weight heparins and heparin analogs |
| PF4 ELISA - IgA and PF4 ELISA - IgM | Detects the rare important non-IgG HIT antibody |

Effective 8/17/2009, the PF4 ELISA - IgG will be performed on all samples submitted for heparin dependent platelet antibody-PF4 testing. The PF4 ELISA - IgA and PF4 ELISA - IgM become available on 8/17/2009. The Serotonin Release Assay will continue to be offered as existing.

If you have any questions regarding our laboratory tests for evaluation of HIT, contact Karin Mani, Client Services Representative at (800) 245-3117, ext. 6083 or Karin.Mani@bcw.edu.

Enclosures: sample reports