

**TO:** All Clients of Strong Memorial Hospital and Highland Hospital Clinical Laboratories  
**RE:** Coagulation Testing  
**DATE:** October 19, 2006

At 12:00am on Tuesday, October 24, 2006, the Automated Laboratory of the University of Rochester Medical Center and Highland Hospital Laboratory will switch to new instrumentation (Diagnostica Stago) for coagulation-related testing. This will be the first of two phases of switching-over to the new platform and will include high-volume tests (eg., PT, PTT, fibrinogen, D-dimer etc.) and factor analyses. The second phase will include more esoteric coagulation tests at SMH and will occur upon completion of assay workups. Attached are individual tables for Strong Memorial and Highland Hospital showing tests involved along with old (before October 24, 2006) and new (after October 24, 2006) reference ranges. Several of the tests merit specific comment.

### **1. PT and INR**

Although sensitivities of the old and new reagents are the same, there is a slight increase in the PT reference range most likely resulting from differences in vendor-specific reagent formulations. In-house correlation studies of INR between old and new assays reveal excellent linear correlation ( $r = 0.98$ ); however, new INR assay results at SMH are lower than old assay results for INR's above 2 (ie., old assay INR values of 2, 3, and 5 correspond to new INR assay values of 1.8, 2.5 and 3.8). Although the INR has been developed to minimize differences among assays, especially as related to monitoring of warfarin therapy; such small discrepancies are well-known. Thus, it should be noted that these changes may result in slight increases in amount of warfarin needed to maintain patients in the usual therapeutic range of 2-3. INR assay results at Highland Hospital remained equivalent.

### **2. PTT as related to heparin therapeutic range**

There is a slight increase in the reference range of the new PTT assay. Use of the PTT for monitoring therapy with heparin is based upon achieving a therapeutic range of heparin between 0.3 and 0.7 U/mL. In-house studies have shown that corresponding to these values, the PTT range for monitoring heparin therapy has increased (old assay, 46 - 70 sec; new assay, 69 - 109 sec).

### **3. D-dimer**

To achieve optimal operation efficiency, the D-dimer assay will change from an ELISA to an immunoturbidimetric methodology. Although units of the old assay (ng/mL) and the new assay ( $\mu\text{g/mL}$ ) are different; they both are based on fibrinogen-equivalent units (FEU) which simply means that the assay is calibrated with fibrinogen completely converted to cross-linked fibrin (in contrast to the other major class of assays that use D-dimer for calibration). In-house studies comparing the old and new assays reveal excellent linear correlation between the two methods ( $r = 0.97$ ). Additionally, in-house reference range studies resulted in a slightly lower value for the upper reference limit at SMH and a slightly higher value at Highland Hospital. To convert new units to old, multiply by 1000.

Questions and comments should be directed to:

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