

Lab Focus

April 2003—periodic insert to 'Scope from Fairview Clinical Laboratories

Sound bites. . . .

NEW COAGULATION TESTING REFERENCE RANGES AND CRITICAL VALUES

Effective Apr. 7, 12 p.m.

Applies to testing performed at Fairview Northland Regional Hospital, Fairview Ridges Hospital, Fairview Red Wing Hospital, Fairview Southdale Hospital, and Fairview-University Medical Center.

New INR

< 30 d	0.81-1.30
1 – 6 mo	0.81-1.17
>6 mo	0.86-1.14
Critical	>5.5

Previous: University Campus: 0.89-1.09; all other sites: 0.85-1.15

New APTT

< 30 d	27-52 s
1 – 6 mo	24-47 s
>6 mo	22-37 s
Critical	>105 s

PTT on premature infants are approx. 20% higher.

Previous: University Campus: 23-33 s, critical >90 s; all other sites: 25-35 s, critical >100 s

New Fibrinogen

All ages	200-420 mg/dL
Critical	< 150 mg/dL

Previous: University Campus: 170-370 mg/dL; all other sites: 170-400 mg/dL

New Thrombin Time

All ages	13-19 s
Critical	> 60 s

Previous: University Campus: 10-20 s; all other sites: 13-18 s

New D-Dimer

All ages	<0.5 ug/mL
Critical	none

Previous: University Campus: 0.2-0.6 FEU/mL; Ridges and Riverside Campuses: negative qualitative

Pediatric reference ranges are approximations based on comparison of adult ranges on our method with pediatric vs. adult values in the literature.¹

¹M Andrew, B Paes, M Johnston. Development of the Hemostatic System in the Neonate and Young Infant. Am J of Ped Hem Onc 12:95-104, 1990.

Coagulation Results Become Standardized Across Fairview Hospitals

To serve patients and physicians better, Fairview Laboratories are standardizing coagulation instrumentation at most sites. Effective April 7, at 12 p.m. Diagnostica Stago coagulation instrumentation will be implemented at Fairview Northland Regional Hospital, Fairview Ridges Hospital, Fairview Southdale Hospital, and both campuses of Fairview-University Medical Center. The instrumentation was recently implemented at Fairview Red Wing Hospital. Fairview Lakes Regional Medical Center refers fibrinogen and thrombin time assays to Fairview-University; they will implement the new instrumentation at a later date. These changes will apply to Fairview clinics that utilize the hospital laboratories for coagulation testing.

The new instruments perform mechanical, spectrophotometric and immunoassay methods. Test quality was the primary determinant in the system-wide decision.

Hemogram to Become CBC with Platelets

The AMA's 2003 CPT coding manual renamed Hemogram as Complete Blood Count (CBC) and added a platelet count. When an order for a CBC is placed, it includes Hemoglobin, Hematocrit, RBC, WBC and Platelet Count. These order changes were implemented late March and name changes will be implemented in FCIS Apr. 16.

Hematology testing should be ordered as follows:

- CBC
- CBC Differential

- Hemoglobin
- Hematocrit
- WBC Count
- Platelet Count

Note: CBC includes Hgb, Hct, RBC, WBC and Plt

Therapeutic Guidelines for Heparin Administration

New therapeutic heparin dosing levels were determined in March, by comparing PTT on the new instrumentation to the "gold standard," antifactor Xa heparin levels. This allowed greater accuracy than comparing PTT levels between new and old methods.

New "High Dose" heparin therapeutic range for DVT & PE (~0.3 to 0.7 units/mL of heparin anti-Xa activity) is **APTT 70-105 s**. Previous therapeutic range: APPT 60-90 s.

New "Low Dose" heparin therapeutic range for CV, vascular, and thrombolytic therapy (~0.15-0.35 units/mL of heparin anti-Xa activity) is **APTT 60-75 s**. Previous therapeutic range: APPT 50-75 s.

High and low heparin dosing levels were based on existing protocols at all sites as well as supported by literature from the Sixth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy:

"When a nomogram is used, it is important to determine the appropriate therapeutic range based on the local laboratory reagent and to adapt the recommended dosage adjustments accordingly. For patients with venous thrombosis or PE, the targeted APTT should be equivalent to a heparin level of 0.3 to 0.7 U/mL by antifactor Xa heparin levels.

“A lower therapeutic range is recommended for patients with acute myocardial ischemia receiving thrombolytic or GPIIb/IIIa antagonist agents, since a lower dose of heparin proved safer and no less effective in these circumstances than the higher-dose regimen established for patients with venous thrombosis. Recognizing that the traditional heparin dosing regimens cause excessive bleeding in patients with acute myocardial infarction who receive thrombolytic therapy, a therapeutic range corresponding to antifactor Xa levels of 0.14 to 0.34 seems reasonable. Failure to adapt nomograms to the therapeutic range could result in dangerous errors in heparin therapy.”¹

¹J Hirsh, TE Warkentin, SG. Shaughnessy, et al. *Heparin and Low-Molecular-Weight Heparin Mechanisms of Action, Pharmacokinetics, Dosing, Monitoring, Efficacy, and Safety. Chest. 2001;119:64S-94S.*

FDP Discontinued: Quantitative D-Dimer Offers Greater Specificity

A new quantitative D-Dimer method replaces both the qualitative D-Dimer assay, Simpli-RED, and the FDP assay at Fairview Northland Regional Hospital, Fairview Ridges Hospital, Fairview Southdale Hospital, and both campuses of Fairview-University Medical Center. The new quantitative D-Dimer is offered 24 hours/day.

D-Dimer is a specific marker of the breakdown of a cross-linked fibrin clot (i.e., fibrinolysis), and an indirect marker of clot formation. Elevated FDP is a marker of both fibrinolysis and fibrinogenolysis. As such, the assay lacks specificity. Its primary clinical application has been in the diagnosis of disseminated intravascular coagulation (DIC). A clear advantage of D-Dimer over the FDP assay is that D-Dimer testing can be performed on a standard

coagulation laboratory (citrate/blue top) sample.

Elevated levels of D-Dimer are present in a wide variety of disorders known to be associated with activation of coagulation:

- Pre-DIC conditions and DIC;
- Sickle cell disease;
- Pregnancy, higher if complicated;
- Renal diseases;
- Arterial thrombosis;
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

With a high sensitivity and negative predictive value for DVT, a negative D-Dimer in conjunction with a negative venous compression ultrasonography (CUS) reliably excludes the diagnosis of DVT, thereby obviating the need for serial CUS testing.

Nigel Key, MD, UM Physicians

CLIA Regulations Have Minimal Impact On Fairview Labs

Revisions published in January to the Clinical Laboratory Improvement Amendments (CLIA '88) of 1988 by the Centers for Medicare and Medicaid Services (CMS) are largely already in effect at Fairview laboratories.

CLIA '88 was enacted in response to public and media concerns about the quality of laboratory testing with the intent that testing should be reliable and accurate regardless of where it was performed. CMS (then the Health Care Financing Agency – HCFA) was authorized to write regulations to administer the law. Because of many concerns and comments the first final rule, containing most of the provisions that we still practice under today, was published in 1992. Additional

changes were published in final rules in 1994, 1997, 1998, and 2000. CMS has indicated the 2003 document is not the "final final" rule! CMS plans to address proficiency testing and laboratory information systems in future documents.

The text of the January 24 final rule can be found at the Federal Register web site: www.access.gpo.gov/su_docs/aces/aces140.html.

The document has been reorganized to eliminate redundancy, distribute quality requirements throughout, and mimic the flow of specimens through the preanalytical, analytical, and postanalytical phases.

The January revisions impact only 22 percent of the 171,000 total U.S. clinical laboratories:

- 13 percent inspected by CMS
- 4 percent inspected by COLA
- 5 percent inspected by CAP, AABB, JCAHO, etc. These, including Fairview, already adhere to more stringent accreditation requirements.

Seventy seven percent of laboratories are not impacted:

- 54 percent performing only waived testing
- 23 percent performing provider performed microscopies.

More complete summaries by Kathy Hansen and Tony Killeen, MD, can be obtained from Mary Lou Pitzen at mpitzen1@fairview.org.

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