Lab Focus

May 2002– periodic insert to 'Scope *from Fairview Clinical Laboratories*

Sound bites. . . .

Important Topics on Page 2

CUMULATIVE SUMMARY REPORTING CHANGES AT METRO HOSPITALS

Based on physician feedback, primarily from Fairview Ridges Hospital and Fairview Southdale Hospital, the format for the laboratory cumulative patient summaries has been modified. Physicians felt that for patients with longer lengths of stay, the horizontal test format (tests listed across the page with dates running down the left column from oldest to most recent) facilitated easier trending of specific tests over time, rather then the vertical test format which lists date across the page with tests running down the left column.

The routine chemistry, hematology, coagulation and urine chemistry sections were modified. The other sections were not changed because they were easier to read in the vertical format or ordered so infrequently that trending was not an issue. This change will be implemented mid-May.

Pat Berger, LIS Director
Jon Wogensen, MD, FRH
John Eckfeldt, MD,PhD, F-UMC
Bruce Trautman, MD, FSH

SPECIMEN REQUIREMENT UPDATE

Lymphocyte Antigen and Mitogen Proliferation (previously called Lymphocyte Blastogenesis: Antigens and Mitogens, Blood)

Referral Laboratory: Associated Regional and University Pathologists (ARUP)

Availability: Test must be scheduled one week in advance. Results are reported within 16 days.

Collection: 10 mL blood in yellow (ACD, Solution A) tube; 3 mL in green (Na heparin).

NEW PCR ASSAY FOR CHLAMYDIA AND GONOCOCCUS

On April 5 the Clinical Microbiology Laboratory at the Fairview-University Medical Center, University campus, transitioned from a ligase chain reaction (LCR) assay to a new technology of target capture, transcription-mediated amplification (TMA) and dual kinetic assay, (GEN-PROBE® APTIMA® Combo 2 Assay) for detection of these two organisms. This assay, a variant of PCR, utilizes target capture for *in vitro* qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* in endocervical and male urethral swab specimens and in female and male urine specimens. The test may be applied to specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease. In comparing different available assays for nucleic acid amplification of these sexually transmitted agents, I based my decision for negotiation and implementation on quality of performance (sensitivity and specificity), efficiency of the assay with simultaneous detection and differentiation of *Chlamydia trachomatis and Neisseria gonorrhoeae* (single reaction tube), minimal manual pipetting, large volume of specimens pass-through, and favorable cost analysis ---including reduction in personnel time. The former LCR assay required repeat testing of all positive *Chlamydia* reactions, which was a burden financially and technically.

In our laboratory we have evolved over time from cell culture to direct fluorescent antibody testing to direct DNA probe assays for *Chlamydia*, and finally to a variant of PCR, called LCR. Published articles have demonstrated that nucleic acid amplification technologies have a significantly higher sensitivity than culture, enzyme immunoassay, or direct DNA probes. Nucleic acid amplification (i.e. PCR) approaches are superior to all other assays for both organisms. The sensitivity and specificity of the new assay for *Chlamydia trachomatis* are 96% and 98%, respectively; for *Neisseria gonorrhoeae* the sensitivity and specificity are 98% and 99%, respectively.

In preparing for a replacement technology, I have studied the other products either on company sites, exhibitions at national meetings, or more recently at a workshop at the University campus for technical staff of the Clinical Microbiology Laboratory. The technical lead in this section, Carol Livdahl, spent a week in training recently at the company. She received additional intensive training on-site at the University campus with representatives of the company. Other members of the section, including: Tameko Krueger, Chi Nguyen, Elizabeth Thonen-Kerr, Giang Van Do and Kathie Williamson received one-on-one training. Congratulations to all of them for their dedication and fast learning curve. We were able to "go live" four days after cessation of LCR testing.

Special thanks to Rick Panning for moving the contractual aspects forward and to Karin Libby for communication to all Fairview sites regarding implementation. We appreciate the valuable input of Jonathan Fering of Gen-Probe for the in-house orientation at all of the Fairview hospitals and clinics that submit specimens for these assays.

As in the past, this assay is run Monday through Friday and on Sundays. If there are questions, you can reach me at 612-273-3665 or ferri002@tc.umn.edu

Patricia Ferrieri, MD
Medical Director
F-UMC Clinical Microbiology Laboratory

TROPONIN CHANGE AT METRO HOSPITALS

Fairview Ridges Hospital, Fairview Southdale Hospital, and Fairview-University Medical Center will change troponin I methodologies over the next few months. This change is under way because of false-positive results and analytic difficulties we have experienced with our patient populations. Studies in the literature have cited false-positive increases in troponin related to residual fibrin, heterophile antibodies and human anti-mouse antibodies in patients' plasma.

Consensus documents recently published by the European Society of Cardiology (ESC), the American College of Cardiology (ACC), and the American Heart Association (AHA) make specific recommendations on the use of biomarkers for the detection of myocardial infarction.

Reference range for the new troponin assay follows. Exact reference or disease-specific ranges may vary slightly pending completion of instrument evaluations:

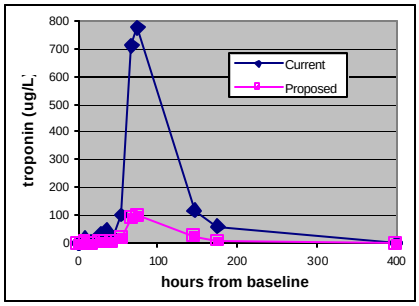
0.00-0.09 ug/L	Normal (up to the 99th percentile of a normal healthy population without myocardial disease)
0.1-0.4 ug/L	Risk stratification: Small increases have been associated with risk of adverse clinical events; e.g., patients with unstable angina and increased troponin are at high risk for short-term adverse cardiac events.
>0.4 ug/L	Diagnostic for acute, evolving, or recent MI if typical rise and gradual fall of troponin with at least one of the following: ▪ Ischemic symptoms ▪ Pathologic Q waves on ECG ▪ ECG changes indicative of ischemia (ST segment elevation or depression), or ▪ Coronary artery intervention, e.g., angioplasty.

Troponin is now the standard biomarker for detection of myocardial damage. Staff must obtain a blood sample at least 6 hours after the onset of symptoms because during the initial hours after an acute myocardial infarction (MI), troponin may not rise to diagnostic levels. Serial sampling remains necessary to make a diagnosis of MI according to the new consensus document. For patients with acute MI, prognosis is somewhat related to the magnitude of troponin increase.

Small increases in troponin clearly above the reference range are indicative of injury to the myocardium; however, elevations are not synonymous with ischemic injury. If the clinical picture suggests ischemic injury is unlikely, other causes of cardiac injury should be investigated; myocarditis, congestive heart failure, certain chemotherapy drugs, etc.

Patients who undergo such interventional procedures as cardiac surgery are likely to have increased troponin as a result of the procedure. Troponin does not discriminate between surgical damage and an acute MI.

Although we've selected different instrumentation for the metro hospitals based on overall test menu needs, the newly introduced assays have similar characteristics, correlate well and provide more rapid turnaround of results. However, all assays give about five to eight-fold lower values than the previous Abbott AxSYM troponin assay. An example of the difference observed between the current Abbott AxSYM assay and one of the new assays are displayed below.



We will continue to use the Abbott AxSYM assay at Fairview Lakes Regional Medical Center and Fairview Northland Regional Hospital where patients with complicating factors are less frequent. Fairview Red Wing Hospital and University Medical Center - Mesabi are currently using an assay with characteristics similar to those being implemented at the metro hospitals.

References:

1. Alpert JS, Thygesen K, Antman E, Bassand JP, et al. Myocardial infarction redefined---a consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction. J Am Coll Cardiol 2000; #36-959-69.
2. Jaffe AS, Ravkilde J, Roberts R, Naslund U, Apple FS, Galvani M, Katus H. It's time for a change to a troponin standard. Circulation 2000; #102:1216-20.
3. Apple FS, Wu AH. Myocardial infarction redefined: role of cardiac troponin testing. Clin Chem 2001; #47:377-9.

Daniel Berntson, MD, FSH
John Eckfeldt, MD, PhD, F-UMC
Michael Steffes, MD, PhD, F-UMC
Jon Wogensen, MD, FRH

IMPLEMENTATION OF COPATH AND HISTOTRAC INFORMATION SYSTEMS

Two new laboratory information systems for Special Diagnostics Laboratories will be implemented on **April 30**.

- The Misys CoPath laboratory information system will be implemented in **Cytogenetics, a portion of Immunophenotyping and Flow Cytometry and Molecular Diagnostics laboratories** at Fairview-University.
- HistoTrac will be implemented in the **Immunology laboratory**.

On **May 14**, **Immunophenotyping and Flow Cytometry** will implement Misys Clinical System *(FlexiLab)* for the remainder of their results.

All new laboratory orders will be processed and reported in the new system starting on April 30. The current laboratory information system will be decommissioned by June1.

As we make this transition, watch for changes in access to results and how results appear on a written report.

- With this implementation, laboratory results from all clinical laboratories at F-UMC, FSH and FRH will be available electronically in FCIS. New results from these laboratories will no longer be available in Abaton or C2K.
- The current systems of paper reporting to other sites will continue until staff change electronic results reporting at all sites. This includes printing or faxing of reports to the medical records departments, site laboratories and/or clinics as appropriate.
- During the changeover, there will be a period of time where results are reported from either the new or old system. All new results will come from Misys CoPath and HistoTrac and display in FCIS. All "old" results will come from the current system. This changeover will be completed before June 1.

Within the laboratory, the change is much more dramatic. Laboratory personnel will have made the significant and difficult change from their old information systems to new software with different functionality and appearance. This transition is an important milestone for the laboratory, IMS and Fairview. Staff have worked hard on this project. Please support the laboratory professionals in these departments as they make this important change. If you have any questions, please contact us as follows:

Kathy Hansen
Laboratory Director
F-UMC
612-273-5090

Cindy Toupal
CoPath Project Lead
IMS
612-672-5868