

Lab Focus

March 2004—monthly insert to 'Scope from Fairview Clinical Laboratories

Sound bites. . . .

Change in ALT Reference Ranges

The Pediatric Oncologists asked the laboratory to review reference ranges for ALT. Results on Fairview metro clinic patients over a six-month period were pulled from the laboratory information system. Based on that data, the adult ranges were validated and the pediatric ranges adjusted slightly. The new reference ranges are:

Female: all ages: 0-50 U/L
Male: 0-20 y: 0-50 U/L;
≥ 20 y: 0-70 U/L

Ketone Method Change at Fairview-University

Beginning Tuesday, Feb. 10, the ketone method used in the laboratory will change. The laboratory will begin using the MediSense Precision Xtra ketone meter, to be consistent with the method currently used on the pediatric units in the hospital.

- The method preferentially measures beta-hydroxybutyrate, which is elevated more reliably in diabetics with ketoacidosis, rather than acetoacetate as did the previous Acetest tablet test.
- The specimen type is heparinized whole blood in a syringe and must be received in the laboratory within 30 minutes from the time of collection.
- Results will be reported as mmol/L concentration of beta-hydroxybutyrate from 0.0-6.0 mmol/L, rather than the current qualitative result of negative, small, moderate or large.
- Reference (normal) range is 0.0 – 0.6 mmol/L; critical range is > 1.5 mmol/L.

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John Eckfeldt, MD, PhD, Medical Director

New *Aspergillus* Antigen Test Available

The Clinical Microbiology Laboratory at Fairview-University Medical Center introduced a new assay in February for *Aspergillus* galactomannan, a constituent of the cell wall of the *Aspergillus* fungus. Since severely immunocompromised patients, e.g., bone marrow transplant patients or leukemia patients on chemotherapy, are at high risk of *Aspergillus* infection, introduction of this assay represents a laboratory advance in assisting in the early diagnosis of a frequently fatal infection.

The Platelia™ *Aspergillus* EIA is an immunoenzymatic sandwich microplate assay and has been approved by FDA for testing of serum only. No other body fluids, such as bronchoalveolar lavages, will be tested. This assay, when used in combination with such other diagnostic procedures as fungal culture, histological examination of biopsy material and radiographic evidence, can aid in the diagnosis of invasive Aspergillosis.

The results will be reported as positive, negative or equivocal. Since a negative result cannot rule out the diagnosis of invasive Aspergillosis, it is recommended that patients at risk for invasive Aspergillosis should be tested twice per week. It is recommended that a second specimen be sent for patients with a positive or equivocal test result.

Because there are reports of positive test results in patients receiving piperacillin/tazobactam who were found subsequently to be free of *Aspergillus* infection, positive test results in such patients should be interpreted with caution and confirmed with other diagnostic tests. There are other sources of fungal galactomannan (such as in *Alternaria*, *Penicillium* and *Paecilomyces* species), so a positive result could reflect infection with one of these fungi. However, these fungi are seen rarely in invasive disease. At this time, the assay is performed twice a week, on Mondays and Thursdays. The test code is ASPGAL.

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Cytology Laboratory Improves Turnaround Time

The Cytology Laboratory improved their turnaround time from collection to sign-out to approximately 5.3 days in January 2004. This is a significant improvement from 8 days in August to October 2003 and 10 days in early 2003.

To compare to how other turnaround times are calculated within Fairview (accession to sign-out), since Jan. 1, we are averaging two days and have

signed-out 78 percent of our cases within two days of accession.

*Klint Kjeldahl
Cytology Supervisor*

New First Trimester Test for Maternal-Fetal Medicine (MFM) Centers

The Maternal Fetal Medicine (MFM) Centers, formerly Perinatal Clinics at Fairview metro hospitals, began using a first trimester test, ULTRASCREE™, for Down's syndrome and Trisomy 18. The new screening tests can be performed in the first trimester, as opposed to the Triple/Quad Screen that is performed in the early part of the second trimester of pregnancy, allowing more time for decisions about diagnostic testing (such as an amniocentesis) and pregnancy management.

The ULTRASCREE test, offered by GeneCare in Chapel Hill, North Carolina, is a combination of a special ultrasound exam performed between 11 weeks, 0 days to 13 weeks, 6 days. The test measures the accumulation of fluid behind the baby's neck, called the nuchal translucency (NT), and a blood test for Free Beta-hCG and Pregnancy Associated Plasma Protein A (PAPP-A) that can be measured from 9 to 14 weeks gestation.

The first trimester serum screen test does not screen for open neural tube defects because the AFP is not evaluated until the second trimester. The patient will also be offered the Triple/Quad screening test that is performed on

a blood specimen collected during the second trimester. Because of gestational age requirements, the two tests cannot be done at the same visit.

GeneCare states that the blood test alone performed between 9 to 14 weeks will come back as "increased risk" for 68 percent of Down's syndrome and 90 percent of Trisomy 18 fetuses. They state that when combining the blood test with the NT, the ULTRASCREE will come back as "increased risk" in 91 percent for Down's syndrome and 97 percent for Trisomy 18.

The ULTRASCREE test will only be offered through the MFM Centers at Fairview-University Medical Center, Fairview Southdale Hospital and Fairview Ridges Hospital because only those locations will have ultrasonographers certified by the Fetal Medicine Foundation (FMF). The ULTRASCREE will only be calculated when the ultrasound exam for NT is performed by a certified clinician. Patients from other locations will be referred to Fairview-University Medical Center, Fairview Southdale Hospital or Fairview Ridges Hospital if they need the test. These patients will meet with the MFM Center certified Genetic Counseling staff prior to the ultrasound exam and serum screen to fully understand the screening nature of this ULTRASCREE test and to review their individual family history and pregnancy risk factors.

The blood samples must be collected on the same day the

ultrasound is performed, and be shipped with the ultrasound results. The blood test(s) are proprietary and are not available from any other reference laboratory.

Turnaround is approximately four to seven days. GeneCare will fax reports to the MFM Centers and to the laboratories. The MFM Centers will relay results to the genetic counselor for immediate review, and the lab will enter the results into FlexiLab so they are viewable in FCIS and other electronic reporting systems.

Under JCAHO standards, selection of reference laboratories is the responsibility of the laboratory medical director, with the approval of the Medical Staff Executive Committee. Gene Care is accredited by CLIA and CAP, and information about the laboratory has been reviewed by Dr. Anthony Killeen of the Fairview-University Medical Center laboratories. Gene Care will be added to the list of reference laboratories that is approved annually by the medical Staff Executive committees at Fairview-University Medical Center, Fairview Southdale Hospital and Fairview Ridges Hospital, the sites of the Fetal Maternal Medicine clinics.

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