

Lab Updates

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Effective November 14, 2011, following changes will be implemented in the following tests:

1. Acceptability Criteria for PTT samples:

The maximum time limit for accepting PTT samples from non-heparinized patients will be 12 hours. If samples can not be tested in 12 hours, the blood samples should be “double centrifuged”. After initial centrifugation of blood samples, transfer plasma to a plastic pour-off tube, and centrifuging again the pour-off tube. The resulting platelet poor plasma is transferred to a new plastic tube and kept frozen at - 20°C. Because of the instability of PTT in the presence of heparin, the maximum time for accepting samples from patients treated with heparin remains 4 hours.

2. Changes in Leukocyte Alkaline Phosphatase (LAP) score reference range:

LAP is an enzyme present in the secondary granules of maturing granulocytes from the myelocyte stage onward. LAP test provides evidence in differentiating chronic myelogenous leukemia (CML) from leukemoid reactions. However, more precise diagnostic tests such as molecular/cytogenetic analyses for BCR/ABL rearrangement should be considered for confirmation of the diagnosis of CML.

The new reference range for LAP score will be 20–95.

The old reference range was 11–95.

For any questions, comments and suggestions please contact:

- Dr. Hongbo Yu, Director of Hematology, at 774-442-9635 or via email at Hongbo.Yu@umassmemorial.org
- Dr. M. Rabie Al-Turkmani, Associate Director Immunology and Hematology, at 774-442-9663 or via email at MRabie.Alturkmani@umassmemorial.org
- Ms. Diane Connor, Manager of Hematology, at 774-442-9091 or via email at Diane.Connor@umassmemorial.org

3. Changes in Sodium (Blood) reference range:

Sodium is the major extra cellular cation and exerts a major influence on plasma osmolality. It plays a Central role in maintaining the normal distribution of water and osmotic pressure. Changes in serum sodium most often reflect changes in water balance rather than sodium balance. Hyponatremia (Defined as serum Sodium less than 135 mmol/L after the exclusion pseudo hyponatremia).

The new reference range for Sodium will be 135–145 mmol/L. The old reference range was 136–145 mmol/L. There are no changes in critical values or specimen requirements.

4. Changes in Cyclic Citrullinated Peptide Antibody, IgG (CCPIGG) reference range:

Antibodies to citrullinated proteins are markers of Rheumatoid Arthritis (RA), especially for early diagnosis of the disease. In some cases these antibodies may be detected many years before the onset of the first symptoms. 2010 American College of Rheumatology guide lines recommends performing at least one serologic test (RF or CCPIgG) and one acute-phase response measure (ESR or CRP) to classify a patient as having or not having definite RA in addition to a history of symptom duration and a thorough joint evaluation. The methodology for CCPIGG will be changed to Multiplex Immunoassay from the existing FEIA method.

The new reference range: Results of <3.0 U/mL are reported as Negative and the results of > 3.0 IU/mL are reported as Positive.

The old reference range was

- <7.0 U/mL: Negative; 7.0–10.0 U/mL: Indeterminate; > 10.0 U/mL: Positive

5. Pneumococcal Pneumonia (Urinary Antigen Test) in Adults:

Streptococcus pneumoniae is a leading bacterial cause of pneumonia globally and is the most common agent leading to hospitalization in all age groups. *S. pneumoniae* are gram-positive, typically lancet-shaped diplococci. It is the most frequently encountered bacterial agent of community acquired pneumonia (CAP). Because of the significant morbidity and mortality associated with pneumococcal pneumonia, septicemia, and meningitis, it is important to have diagnostic test methods available that can provide a rapid diagnosis.

Detection of *S.pneumoniae* C-polysaccharide in urine has been demonstrated to be a useful rapid confirmatory test for pneumococcal infections in adults with sensitivity of 74% and specificity of 94%. Unfortunately the test has poor specificity in children due to detection of pneumococcal nasopharyngeal colonization.

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A positive result is indicative of pneumococcal pneumonia. A negative result does not exclude *S. pneumoniae* infection. A diagnosis of *S. pneumoniae* infection must take into consideration all test results, culture results, and the clinical presentation of the patient. *S. pneumoniae* vaccine may cause false-positive results, especially in patients who have received the vaccine within 5 days of having the test performed.

Effective October 24, 2011, S. Pneumonia Urinary antigen test will be performed at UMASS Clinical Laboratories. Random Urine specimen (5mL) is required.

For any questions, comments and suggestions please contact:

- Dr. L.V. Rao, Director of Core Laboratories at 774-442-9615 or via email at Lokinendi.Rao@umassmemorial.org
- Dr. M. Rabie Al-Turkmani, Associate Director of Immunology & Immunoassay at 774-442-9663 or via email at MRabie.Alturkmani@umassmemorial.org
- Ms. Rachel Ambacher, Manager of Immunology & Immunoassay at 774-442-9065 or via email at Rachel.Ambacher@umassmemorial.org
- Ms. Judy Barron, Manager of Automated Chemistry at 774-442-9616 or via email at Judy.Barron@umassmemorial.org

6. Cystic Fibrosis CF100Plus panel (Mnemonic: CF100PLUS)

An extended CF100Plus panel for Cystic Fibrosis CFTR gene mutation screening will be offered by the UMass Memorial Molecular Diagnostics Laboratory starting November 8, 2011. This test will be offered in addition to the Invader CFTR InPlex panel (Hologic) that screens for 41 CFTR mutations.

The CF100PLUS assay is designed for screening individuals at high risk:

- a) Partners of women who are heterozygous for a CFTR mutation;
- b) Individuals with a family history of known or unknown mutations.

Methodology

This expanded CF100Plus mutation panel tests for 120 mutations. The amplification of DNA fragments around the mutation sites by polymerase chain reaction is followed by an extension reaction and fragment analysis by MALDI-TOF mass spectrometry.

Changes in mutation detection rates depending on the number of tested mutations by ethnicity:

Mutation Detection Rate	Caucasians	Hispanic	African American	Asian	Ashkenazi
ACMG/ACOG 23 mutations (%)	88.3	71.7	64.5	48.9	94
Invader CF 41 mutations (%)	89	74	66	55	94
CF100Plus test is more than (%)	90.6	80.9	72	55	94

Assay Limitations

1. The results obtained using the CF100plus assay should be used and interpreted in the context of a full clinical evaluation.
2. This test probes for 120 Cystic Fibrosis transmembrane conductance regulator (CFTR) mutations/variants out of the more than 1300 which have been identified.
3. As with any hybridization-based assay, underlying polymorphisms or mutations in primer-binding regions can affect the alleles being probed and, consequently, the calls made.
4. Genotype-phenotype correlations for rare mutations are based on limited reported clinical cases and can be highly variable and inconsistent, ranging from benign to severe phenotypes; as a result, clinical conclusions should be made with caution.

Reports

The report will list all mutations tested by the CF100PLUS test. In carrier screening, a heterozygous result indicates that the individual carries a CFTR mutation on one allele. We will no longer call the result heterozygous when the individual will be heterozygous for a benign variant. However, positive variants will be listed in the text of the report.

The assay will be performed twice a week with a TAT of 8-10 days. A signed consent form is required for carrier screening.

For any questions, comments and suggestions please contact:

- Dr. Edward Ginns at 508-856-8134 or Dr. Marzena Galdzicka at 508-856-4384