

#### **BLOOD COLLECTION DEVICE CHANGE**

Puncture Guard needles are no longer being manufactured. We have been researching new products and have decided to use the following:

For Regular Needles

- 21g Kendall-Magellan straight needle with vacutainer attached
- 22g Kendall-Magellan straight needle with vacutainer attached

For Difficult sticks only

- 21g Kawasumi butterfly needle set, adaptor and vacutainer separate
- 23g Kawasumi butterfly needle set, adaptor and vacutainer separate

The entire collection device should be disposed of in a rigid, puncture-resistant bio-hazard needle container.

We currently have some Puncture Guard stock items left, so you may receive either product when you order these supplies.

If you would like additional information on using the new devices, please contact Laboratory Client Relations at 847-5121 1-800-991-2799.

#### **PROVIDER ON CALL CHANGES**

All critical or stat values for outpatients will be called directly to the requesting physician location. During off hours the laboratory relies on the Fletcher Allen Call Center to help us contact the correct clinician to receive the result. Please remember that if you make changes to the monthly provider on-call schedule after the schedule has been sent to the call center you need to contact the call center by phone at 802-847-2700, fax 802-847-1157 or email [call-center-all@vtmednet.org](mailto:call-center-all@vtmednet.org) to make them aware of the change.

Any test ordered with a request of "Please call results" will be called to the ordering location and will not go through the call center. Any test ordered with a request of "Please fax results" will be faxed to the ordering location.

*Thank you*

#### *Lab Operations*

Blood Collection Device Change  
Provider On-Call Changes

#### *Test News*

Amniotic Fluid AFP Reporting  
Insulin Reference Range Update  
Hepatitis B Viral DNA Assay  
A1c Reference Range Update  
Cessation of LAP Testing  
Change in Reference Lab: HIT

#### *Compliance Update*

Update on Medicare LCDs:  
BNP Testing  
hsCRP Testing  
Update on Reflex Testing  
Policy:  
Cytogenetic Testing On Soft  
Tissue And Bone Tumors

# TEST NEWS

## AMNIOTIC FLUID AFP REPORTING

On April 14, the Chemistry Laboratory will change the reporting units for amniotic fluid AFP from ng/mL to µg/mL. The new units correspond to how other laboratories, as well as the College of American Pathologists and New York State are reporting amniotic fluid AFP. The report format will not change. The conversion factor from ng/mL to µg/mL is ng/mL divided by 1000.

## INSULIN REFERENCE RANGE UPDATE

Effective April 14, 2008, the Chemistry Laboratory will update the reference range for Insulin. The assay is performed on the Immulite 2500 analyzer and is a solid phase, two-site chemiluminescent immunometric assay. Based on a small reference range study performed on laboratory volunteers, the new reference range for Insulin will be <29 µIU/mL (previously 6 to 27 µIU/mL). This update correlates with information provided by the manufacturer for expected values on apparently healthy laboratory volunteers which yielded a median of 9.3 µIU/mL and a lower 95% range of up to 29.1 µIU/mL.

Reference: Immulite 2500 Insulin Product Insert, Siemens Healthcare Diagnostics, December 29, 2006.

## HEPATITIS B VIRAL DNA ASSAY

Beginning April 1, 2008, the Chemistry Laboratory will no longer offer the Hepatitis B Viral DNA Assay by the branched-DNA method (Mayo test 82416). This has largely been replaced by the Hepatitis B Virus (HBV) DNA Detection and Quantification by Real-Time PCR (Mayo test 88634) because of its greater sensitivity and wide dynamic range. It should be noted that these tests should not be used for initial evaluation of patients with HBV infection. Laboratory evaluation of HBV status should begin with HBV serological marker tests, including Hepatitis B Surface Antigen (HBsAg). A positive or measurable HBV DNA level should not be used for the diagnosis of chronic HBV infection without the confirmed presence of HBsAg. A negative result does not exclude the presence of HBV DNA.

## A1C REFERENCE RANGE UPDATE

Effective February 11, 2008, the Chemistry Laboratory updated the Hemoglobin A1c reference range to reflect 2008 American Diabetes Association guidelines. The updated reference range is as follows:

Normal range <6%

ADA guidelines:

The A1c goal for nonpregnant adults in general is <7%

The A1c goal for selected individual patients is as close to normal (<6%) as possible without significant hypoglycemia.

*If you have any questions or comments concerning any of these changes, please contact Dr. Greg Sharp in the Chemistry Laboratory through Laboratory Customer Service or e-mail [gregory.sharp@vtmednet.org](mailto:gregory.sharp@vtmednet.org)*

## **CESSATION OF LAP TESTING**

Effective January 29, 2008, the Hematology Laboratory discontinued the Leukocyte Alkaline Phosphatase (LAP) testing. The LAP test is a cytochemical staining assay that was developed decades ago to assist in the diagnosis of chronic myelogenous leukemia (CML); it was also found to be useful in supporting the diagnosis of polycythemia vera (PV). In neither disease was the test diagnostic, and other testing, including cytogenetic or clinical measurements, were required to firmly establish or exclude the diseases. There are few, if any, other indications for this test.

The LAP test has been rendered obsolete by the emergence of two other assays. In the patient for whom CML is a consideration, fluorescent in situ hybridization (FISH) testing of a peripheral blood specimen for the characteristic chromosomal aberration, the t(9;22)(bcr/abl) (Philadelphia chromosome), is the test of choice. For PV, testing a peripheral blood specimen for JAK2 mutation testing is preferred. The FISH test is performed in the FAHC lab; the JAK2 test is sent to Mayo Medical Labs. For providers who feel that LAP testing is essential, the assay is still being offered by Mayo.

### **Test Information:**

**FAHC TEST:** FISH for t(9;22)

**Sample Requirements:** Sodium heparin tube (green top)

**Schedule:** Run Weekly, Day Varies

**Mayo TEST:** JAK2 Mutation Testing

**Mayo Test Number:** 83872

**Sample Requirements:** EDTA tube (purple top)

**Schedule:** Monday - Friday

**Mayo Test:** Leukocyte Alkaline Phosphatase (LAP) Score

**Mayo Test Number:** 9699

**Sample Requirements:** 5 well made peripheral blood smears (fingersticks). All slides should be air dried, unfixed and unstained.

**Schedule:** Monday - Friday

## **CHANGE IN REFERENCE LAB: HEPARIN-INDUCED THROMBOCYTOPENIA (HIT)**

Effective February 11, 2008, FAHC will send specimens for heparin-PF4 antibody testing to Mayo Medical Laboratories (MML Test Code: 81904) instead of the Blood Center of Southwestern Wisconsin. This change in laboratories has been made in order to shorten the turnaround time.

### **Reporting Name: Heparin-PF4 Ab (HIT)**

#### **Result Reporting:**

Formatting of results will change, as the new reference laboratory will provide three-part results consisting of:

- Percent reactivity
- Percent heparin inhibition
- Interpretation

The percent reactivity in the new format is analogous to the OD units previously reported; an OD reading of 0.4 corresponds to 20% reactivity by the new assay, and an OD of 1.0 to 50-56% reactivity.

#### **Guide to interpretation of results of the new assay:**

##### **Negative**

- Reflects a percent reactivity of less than 20% (OD < 0.4 in the old format).
- Heparin inhibition is not tested in this circumstance.
- As with the previous assay, a negative test result has a high negative predictive value for ruling out HIT.

##### **Positive**

- Reflects a percent reactivity greater than 40% and a heparin inhibition of greater than 50%.

##### **Equivocal**

- Reflects either of two circumstances: 1) the percent reactivity is between 20 and 40%, or 2) heparin inhibition is not present when percent reactivity exceeds 40%.
- With the previous assay, results in this range would have been reported as positive, but they would have been low level positives, which are known to have a low positive predictive value for the clinical diagnosis of HIT.
- Equivocal interpretations require careful clinical correlation, and additional testing may be necessary to better characterize the patient's clinical disease.

*Please direct any questions about this testing change to Ted Bovill, M.D., John Lunde, M.D., Ron Bryant, M.D., or Michael Lewis, M.D. through Customer Service, 847-5121 or 1-800-991-2799.*

# COMPLIANCE UPDATE

## UPDATE ON LCD's: MEDICARE LOCAL COVERAGE DECISIONS (LCDS)

Medicare has released the following new Local Coverage Decisions. They are effective April 1, 2008.

### 1. B-type Natriuretic Peptide (BNP) Testing

B-type Natriuretic Peptide is a cardiac neurohormone produced mainly in the left ventricle of the heart. BNP is secreted in response to ventricular volume expansion and pressure overload, factors often found in congestive heart failure (CHF). When used in conjunction with other clinical information, rapid measurement of BNP is useful in establishing or excluding the diagnosis and assessing the severity of CHF in patients with acute dyspnea. BNP testing is also used to predict the long-term risk of cardiac events or death across the spectrum of acute coronary syndromes when measured in the first few days after an acute coronary event.

#### **Indications:**

BNP measurements may be considered reasonable and necessary when used in combination with other medical data such as medical history, physical examination, laboratory studies, chest x-ray, and electrocardiography:

- To distinguish cardiac cause of acute dyspnea from pulmonary or other non-cardiac causes.
- To distinguish decompensated CHF from exacerbated chronic obstructive pulmonary disease (COPD) in a symptomatic patient with combined chronic CHF and COPD.
- As a risk stratification tool (to assess risk of death, myocardial infarction or congestive heart failure) among patients with acute coronary syndrome (myocardial infarction with or without T-wave elevation and unstable angina).

To view the policy in its entirety: [http://www.ahpnhmedicare.com/files/documents/l26375\\_lcd\\_notice\\_ngs.htm](http://www.ahpnhmedicare.com/files/documents/l26375_lcd_notice_ngs.htm)

### 2. High Sensitivity C-Reactive Protein (hsCRP) Testing

High-sensitivity C-reactive protein (hsCRP) is a marker of inflammation with detection levels as low as 0.07 mg/L in the blood. Prior to the development of the high-sensitivity assays, the lower limit of detection of CRP was 3 mg/L.

#### **Indications:**

Testing for hsCRP will be considered medically necessary for the assessment of coronary heart disease (CHD) risk assessment and management when ALL of the following criteria are met:

- The patient is considered at intermediate risk (10-20% of CHD per 10 years) using the NCEP Adult Treatment Panel III (ATP III) guidelines.
- The hsCRP level is being obtained to determine whether lipid-lowering pharmacologic therapy is needed for the primary prevention of CHD.
- The patient is metabolically stable and without obvious inflammatory or infectious conditions.
- The test may be obtained two times, optimally two weeks apart, to obtain an average level. Results of > 10 mg/L should be discarded and not repeated for at least two weeks after the source of infection or inflammation has been identified and cleared.

To view the policy in its entirety: [http://www.ahpnhmedicare.com/files/documents/l26445\\_lcd\\_notice\\_ngs.htm](http://www.ahpnhmedicare.com/files/documents/l26445_lcd_notice_ngs.htm)

*If you have questions regarding these new coverage decisions please contact Janet Schroeter (84709435) or Kathy Nadeau (847-0930).*

**UPDATE ON REFLEX TESTING POLICY:  
CYTOGENETIC TESTING ON SOFT TISSUE AND BONE TUMORS**

In addition to the current reflex testing policy in surgical pathology for submitting tissue for Cytogenetic analysis from renal tumors and fatty tumors, tissue from soft tissue tumors and bone tumors, including certain pediatric tumors, will be routinely submitted for Cytogenetic analysis.

Data have emerged demonstrating the utility of Cytogenetics as an adjunct to traditional diagnostic methods such as histologic examination with H&E stains as well as immunohistochemical stains. Cytogenetic analysis is considered integral to the diagnosis of some soft tissue and bone tumors, especially in cases which pose a histologic challenge. Soft tissue and bone tumors with well known chromosomal translocations and gene rearrangements include Ewing sarcoma/PNET, desmoplastic small round cell tumor, extraskeletal myxoid chondrosarcoma, synovial sarcoma, alveolar rhabdomyosarcoma, low grade fibromyxoid sarcoma and inflammatory myofibroblastic tumor, to name a few.

Initial Test	Reflex Criteria	Reflex Test	Additional CPT
Soft Tissue or Bone Tumor	Enough Tumor to sample	Cytogenetics	88291, 88264, and 88237 or 88239

As with all reflex testing, the ordering provider can choose to decline the reflex testing by checking the appropriate box on the Surgical Pathology requisition.

*If you have questions regarding these new coverage decisions please contact Janet Schroeter (847-9435) or Kathy Nadeau (847-0930).*