An Update on testing for thrombotic disorders at Mercy Clinical Laboratory (MCL)

Testing for thrombotic disorders is an evolving science. New methodologies are constantly being introduced which can cause frustration when ordering. Unfortunately, the treatment for thrombosis often interferes with several key diagnostic tests. MCL has developed new panels which will assist clinicians with ordering appropriate testing. Our Lupus Anticoagulant (LAC) and Antiphospholipid Antibody (APA) testing strategies are based on the 2005 International Consensus in Classification Criteria for Antiphospholipid Syndrome (APS)1. This consensus is largely based on the 1999 publication of the Sapporo Criteria2. The only significant modification between the two publications is the recommended inclusion of beta-2 glycoprotein antibodies. Approximately 3-10% of APS patients will test positive for only anti-beta-2 glycoprotein antibodies. Another benefit of providing beta-2 and anti-cardiolipin antibody is the fact these tests are not affected by anticoagulant therapy. And while LACs and APAs are common acquired causes of unexpected thrombosis in the general population, inherited disorders should also be considered in patients less than 50 years of age. An explanation of the test panels is summarized below. We are now able to provide all of the following tests “in-house” which will result in improved turn-around-time and testing quality. While these panels will detect the most common causes of thrombophilia, other etiologies to consider include myeloproliferative neoplasia, paroxysmal nocturnal hemoglobinuria, malignancy, etc. For additional questions please call Matthew Andres D.O. at (515) 247-4467.

(Continued on page 2 ...)
Fecal Lactoferrin

MCL is pleased to announce that Lactoferrin detection is now offered in our Test Menu. This test is an alternative choice to the Fecal White Blood Cells (FWBC). Both tests detect the presence of white blood cells in stool specimens, indicating an inflammatory diarrheal disease. The Lactoferrin assay, however, is significantly more sensitive than the FWBC microscopy.

Diarrheal diseases can be classified into inflammatory and non-inflammatory diarrhea. Non-inflammatory diarrheas include those caused by viruses and most parasites and are, for the most part, effectively treated with simple oral rehydration therapy. Inflammatory diarrheas, on the other hand, tend to be more serious and need to be followed up with more extensive testing. This type of diarrhea is caused by pathogens such as Shigella, Salmonella, Campylobacter jejuni, and Clostridium difficile. In inflammatory diarrheas, fecal leukocytes are found in feces in large numbers.

Determining the presence of fecal leukocytes by microscopy has disadvantages. Microscopy is not standardized and specimens must be examined within minutes of collection to be accurate. The test can be difficult to interpret and storage of specimens overnight before examination may result in lower sensitivity due to cell lysis. Some enteric pathogens, such as Clostridium difficile, produce toxins that lyse leukocytes and other cells. As a result, leukocytes may not be visible late in the infection even though there is severe inflammation.

The Lactoferrin assay overcomes the problems of microscopy by utilizing immunochromatography technology. The assay detects elevated levels of lactoferrin in fecal samples. Lactoferrin is very stable and is not degraded during infections by the toxins of pathogens such as C. difficile.

Please note: This test may not be appropriate in immunocompromised persons. Additionally, fecal samples from breast-fed infants should not be used with this assay.

Specimens must be submitted in a clean container without preservative. Refrigeration is preferred, but room temperature specimens are also acceptable. Specimens are stable for up to two weeks.

<table>
<thead>
<tr>
<th>Lactoferrin</th>
<th>CPT: 83630</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient / Insurance Cost:</td>
<td>$74.00</td>
</tr>
<tr>
<td>Client Account Cost:</td>
<td>$43.50</td>
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(Thrombotic Disorders continued ...)

As of December 14, 2010, the following panels will be available:

Lupus Anticoagulant (LAC) Profile
This short simple screen will detect most patients with a LAC and/or APAs. If this test is positive, repeat testing in 12 weeks is recommended to confirm the diagnosis. Of note: these tests ARE AFFECTED BY COUMADIN and occasionally heparin. If the patient is anticoagulated, caution must be used in interpreting the results.

1. Prothrombin Time (PT)
2. Lupus Sensitive Partial Thromboplastin Time (PTT)
3. Dilute Russell Viper Venom Time (dRVVT)
4. StaClot (if indicated)

Antiphospholipid Antibody (APA) Profile
This screen will detect nearly all patients with a LAC and/or APAs. If this test is positive, repeat testing in 12 weeks is again recommended to confirm the diagnosis. Including beta-2 glycoprotein and antcardiolipin antibodies in this panel is helpful in that they not only add increased sensitivity and specificity, but these tests are NOT AFFECTED BY ANTICOAGULATION THERAPY.

If a patient is confirmed to have an APA and placed on Coumadin, beta-2 glycoprotein and antcardiolipin antibody monitoring can be performed.

1. LUPUS ANTICOAGULANT WORK-UP
   a. Prothrombin Time (PT)
   b. Lupus Sensitive Partial Thromboplastin Time (PTT)
   c. Dilute Russell Viper Venom Time (dRVVT)
   d. StaClot (if indicated)
2. BETA-2 GLYCOPROTEIN ANTIBODIES (IgG, IgM, & IgA)
3. ANTICARDIOLIPIN ANTIBODIES (IgG, IgM, & IgA)

Hypercoagulable Profile
This is the preferred work up for patients <50 years of age who seek medical attention for an unexpected clot (DVT, PE, etc). This panel includes both acquired and inherited causes of thrombosis. If the homocysteine level is increased, molecular testing for the MTHFR gene is recommended. Of note: because this panel includes expensive molecular testing, this full panel should only be ordered once. If the test results in non-specific findings, please use the above listed panels for follow-up and monitoring.

1. LUPUS ANTICOAGULANT WORK-UP
   a. Prothrombin Time (PT)
   b. Lupus Sensitive Partial Thromboplastin Time (PTT)
   c. Dilute Russell Viper Venom Time (dRVVT)
   d. StaClot (if indicated)
2. BETA-2 GLYCOPROTEIN ANTIBODIES (IgG, IgM, & IgA)
3. ANTICARDIOLIPIN ANTIBODIES (IgG, IgM, & IgA)
4. PROTEIN C, PROTEIN S, ANTITHROMBIN III ACTIVITY
5. PROTHROMBIN GENE MUTATION
6. FACTOR V LEIDEN GENE MUTATION
7. HOMOCYSTEINE (PLASMA)
Mercy Clinical Laboratory implements improved HIV 1-2 testing

Mercy Clinical Laboratory has recently introduced Abbott’s ARCHITECT HIV Ag/Ab Combo assay for detection of HIV infection. This method, recently approved by the FDA, allows for the detection of antibodies to HIV-1, HIV-2 as well as detection of the HIV-1 p24 antigen.

HIV-1 p24 antigen is produced by the virus immediately after infection, whereas antibodies are developed days later as the body works to fight off the infection. The ability to detect the HIV-1 p24 antigen will provide an earlier diagnosis of HIV infection which is important in controlling the spread of the disease.

The ARCHITECT HIV Ag/Ab Combo assay is a chemiluminescent microparticle immunoassay (CMIA). A reactive result using this assay does not distinguish between the detection of HIV-1 antibody, HIV-2 antibody or HIV-1 p24 antigen. Samples found to be reactive are referred for confirmatory testing by Western Blot.

<table>
<thead>
<tr>
<th>Preferred Specimen:</th>
<th>Collect 5 ml of blood in a Green Top PST tube</th>
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<tbody>
<tr>
<td>Alternate Specimen:</td>
<td>Collect 5 ml of blood in a Gold Top Serum SST</td>
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<tr>
<td>CPT Code:</td>
<td>86703</td>
</tr>
<tr>
<td>Methodology:</td>
<td>CMIA</td>
</tr>
<tr>
<td>Dept:</td>
<td>Chemistry</td>
</tr>
<tr>
<td>Turn-around time:</td>
<td>Testing is performed Monday–Friday</td>
</tr>
<tr>
<td>Specimen Stability:</td>
<td>Refrigerated 7 days. Freeze if &gt; 7 days</td>
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Test Update
Platelet Antibody

<table>
<thead>
<tr>
<th>Preferred Specimen:</th>
<th>Collect 6 ml of Blood in a Red Top tube with no additive</th>
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<tbody>
<tr>
<td>CPT:</td>
<td>86022</td>
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<tr>
<td>Methodology:</td>
<td>Solid-phase EIA</td>
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<tr>
<td>Dept:</td>
<td>Referred – Mayo Medical Laboratory</td>
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<tr>
<td>Specimen Stability:</td>
<td>Frozen</td>
</tr>
<tr>
<td>Note:</td>
<td>Draw in a Red top tube with no additive. Allow tube to clot for 30 minutes and then centrifuge. Aliquot a minimum of 1.0 ml of serum and freeze. Include major diagnosis and the reason for suspecting the presence of Platelet Antibodies.</td>
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Updates

WHY I JOINED MERCY CLINICAL LABORATORY...

Dale Cheuvront

I joined Mercy Clinical Laboratory as the Anatomic Pathology Supervisor in August. I graduated from University of Nebraska-Lincoln with a B.S. in Microbiology. I received my Cytotech training at the University of North Dakota. I passed the Cytology specialty exam and have been a cytotech for 31 years, most of the time at Creighton University Medical Center. The last 8 years, I served as Anatomic Pathology Supervisor there.

Darcy Brown

Hi, my name is Darcy Brown. I joined Mercy in September as the Phlebotomy Supervisor. I received my degree in Clinical Laboratory Science from the University of Cincinnati and have a BS in Business from Upper Iowa University. Most recently, I worked as a generalist at Lutheran and Methodist on the evening shift. Before that I worked at a 25 bed critical access hospital in north-western Wisconsin. I grew up in Norwalk, Iowa, so I am glad to be back in the Des Moines area, and excited to be at Mercy.
MCL Newsletter Contributors

Mercy Clinical Laboratory has made several updates to the MCL Website. These include:

1. MCL Test Catalog which links to the MCL Atlas test catalog. This provides current test requirements including tube type, volume, storage temperature, stability, cause for rejection, and day of testing. The test catalog also provides CPT codes and pricing.

2. MCL Client Manual. The MCL Client Manual contains test requisition information. It also provides collection information for Microbiology and Cytology specimens, critical value ranges and therapeutic drug levels.

3. Collection brochures and forms. The collection brochures include collection instructions for 24 hour and routine urine, semen analysis, sputum, and stool. These forms are printable for client and patient convenience. The MCL Supply Order Form, Lead Form, and Allergen Test Request are also printable from the website.

4. Accreditation and licensure certificates. CLIA, CAP, and AHSI certificates are available. All MCL Newsletters and Updates are also available on the MCL website.

5. Any announcements from Mercy Clinical Laboratory will be posted as well. The additions to the MCL website will provide a quality service to our clients.