

**September 2009**  
**Volume 1 • Issue 8**

## Laboratory Professional Staff

Dale Andres, DO  
*Laboratory Medical Director*

Avina Kolareth, MD  
*Pathologist*

Vijaya Dhanwada, MD  
*Pathologist*

Matt Andres, DO  
*Pathologist*

Steve Lee, MD  
*Pathologist*

Ramona Thompson, MD  
*Pathologist*

Carolyn Woon, MD  
*Pathologist*

## MCL Management

Nancy Mathahs, MHA, MT(ASCP) SM  
*Director, Laboratory Services*

Teri Reiff, MT (ASCP)  
*Manager, Core Laboratory*

Elizabeth Smith, MT (ASCP), MBA  
*Manager, Specimen Management Services*

Sharon Jones, MT (ASCP)  
*Manager, Specialty Services*

### In this Issue:

- Changes to Lipid Reporting
- Determining Medical Necessity
- Pretransfusion Orders
- New Test Methodology: HIT Antibodies

## MCL Makes Changes to Lipid Reporting

Effective July 30, 2009, Mercy Clinical Laboratory will report results of lipid assays according to the clinical guidelines for cholesterol testing and management (NCEP ATP III). These guidelines are intended to inform, not replace, the physician's clinical judgment, which must ultimately determine the appropriate treatment for each individual.

In addition to improved guidance for interpretation of lipid assays, a new calculation for non-HDL Cholesterol will be included in the Lipid Panel. This calculation is the difference between the total Cholesterol concentration and the HDL Cholesterol concentration. The non-HDL Cholesterol calculation estimates the sum of LDL+VLDL cholesterol present in the patient's sample. For patients with high triglyceride levels (200-499 mg/dl), the non-HDL cholesterol becomes a secondary target of therapy.

ATP III guidelines for lipid assays reported after July 30, 2009 will be evaluated based on the following ATP III guidelines:

<b>Cholesterol</b>	<b>&lt; 200 mg/dl Desirable</b> <b>200-239 mg/dl Borderline High</b> <b>≥ 240 mg/dl High</b>
<b>Triglyceride</b>	<b>Normal: &lt; 150 mg/dl</b> <b>Borderline-high: 150-199 mg/dl</b> <b>High: 20-499 mg/dl</b> <b>Very high: ≥ 500 mg/dl</b>
<b>HDL Cholesterol</b>	<b>&lt;40 mg/dl Low</b> <b>≥ 60 mg/dl High</b>
<b>LDL Cholesterol</b>	<b>&lt; 100 mg/dl Optimal</b> <b>100-129 mg/dl Near Optimal / Above Optimal</b> <b>130-159 mg/dl Borderline High</b> <b>160-159 mg/dl High</b> <b>≥ 190 mg/dl Very High</b>
<b>Non-HDL Cholesterol</b>	<b>≤ 129 mg/dl</b>

Please call MCL Marketing at 247-4492 with any questions.

## Welcome

Mercy Clinical Laboratory welcomes Ramona Thompson M.D. as our newest pathologist. Dr. Thompson holds a Bachelor degree and graduated from Medical School at the University of Minnesota. She completed her residency in pathology and a fellowship in cytopathology at the University of Minnesota. Dr. Thompson is available for consultation and can be reached at 643-8638.



## Determining Medical Necessity

In the 1990s, the Office of Inspector General (OIG) and the Health Care Financing Administration (HCFA, now called CMS) began a series of investigations that dramatically altered the landscape of healthcare coding and billing. The goal was to determine the appropriateness of Medicare payments. Medical necessity is required under Section 1862(a) (1) (A) of the Social Security Act. This section lays out Medicare's regulatory structure for determining medical necessity by stating, "No payment shall be made for items or services that are not reasonable and necessary." In addition, the Medicare guidelines say, "A test may be considered medically appropriate, but nonetheless excluded from Medicare coverage" (Federal Register, 11/25/2001, p. 58810). The Balanced Budget Act of 1997 (BBA) requires an ordering physician/provider to submit diagnosis information to the laboratory when ordering a test for which that information is required for payment by the Medicare Program.

In accordance with these regulations, as well as our own corporate compliance directives, Mercy Clinical Laboratory (MCL) provides the **MCL Medical Necessity Manual**. This red 3-ring binder contains current National Coverage Decision (NCD) & Local Coverage Decision (LCD) information, as well as Screening and Frequency reminders. MCL representatives schedule in-services to educate physician/providers and staff in how to effectively comply with the Medical Necessity guidelines for laboratory testing. If your facility needs a current copy of these guidelines or if you would like to schedule an in-service, please call MCL Marketing at 515-247-4492.

### FAQ's about Medical Necessity:

#### What is an ABN?

ABN is the acronym for Advance Beneficiary Notice. The ABN is a mechanism devised by HCFA (CMS) to protect beneficiaries from receiving and being billed for services that are not covered by Medicare, without the beneficiary being warned that they may be responsible for the charges.

#### What is a local medical review policy (LMRP)?

Medicare has identified a handful of procedures that it will cover for screening purposes. In most cases, however, Medicare does not pay for screening or routine tests. They only pay for tests used for treatment and diagnosis of disease. Since many tests can be used in either case, HCFA (CMS) needed a way to define screening versus diagnostic use of the tests. The LMRP defines the Medicare approved use of a test by specifically indicating what clinical circumstances justify the use of the test. These policies contain a list of ICD-9 codes that the Carrier or Fiscal Intermediary (FI) will accept for payment. The diagnosis information must be included on the claim form. Everything else is not considered "reasonable and necessary" use of the test and the claims are rejected as not being medically necessary.

#### When the government says a test must be "medically necessary", what does that mean?

The government's interpretation of medical necessity is based on language contained in the Social Security Act rather than a clinical definition. That means it is a test necessary for the diagnosis and/or treatment of disease. It means that the test is essential to diagnosing and/or treating the patient for the reason the patient is seeing the physician at the time the test is ordered. Routine tests and tests used to screen for disease in the absence of signs, symptoms or histories are not considered medically necessary by Medicare.

#### Who is the best person to talk to the patient about the ABN?

The physician/provider can explain to the patient why they think the test should be done, even though it is outside of the Medicare guidelines. Informed consent to allow the patient to make a choice about having a test done is one of the purposes of the ABN. The reason for the testing can only come from the physician/provider ordering the test. Once the patient reaches the laboratory, the only information staff can offer the patient is that they will likely be billed if they have the test done. The laboratory should not speculate on why a physician/provider ordered a test unless the physician has stated this information on the requisition or order (such as indicating a screening test).

## A Review of Pretransfusion Orders

The physician's orders initiate what testing is performed by the Transfusion Service. The blood specimen for testing must be collected after properly identifying the patient. Compare the patient name and medical record number on the requisition to the patient's armband. They must match exactly. If the patient is awake, ask him to state his first and last name and birth date for confirmation. Then the sample may be drawn and labeled at the bedside.

Blood typing is a test that identifies blood group antigens belonging to the ABO system, and the presence or absence of the D antigen in the Rh system.

Antibody screening is a test to detect atypical antibodies in the serum that may have been formed as a result of transfusion or pregnancy. These antibodies may cause incompatibilities with the transfused blood.

The scope of orders may be as simple as a "Hold for possible orders" to Type and Crossmatch.

- **"Hold" orders:** the properly drawn, labeled and patient banded specimen will be held in the Blood Bank for 3 days pending possible orders. No testing will be done. Notation on the requisition should state "Hold for possible orders" or a "Blood Band" for obstetrical patients may be ordered.
- **TYPE and SCREEN** - This is the test of choice if transfusion is not expected, but possible. The patient's blood is tested for:
  - ABO group, Rh type and unexpected blood group antibodies (antibody screen). The blood specimen is stored in the Blood Bank for future crossmatching if a transfusion is needed within the next 3 days. (call Blood Bank and send a new Requisition with Physician orders noted). If the antibody screen was negative, it should only take 10 to 15 minutes to complete the crossmatch. The required documentation is completed in a few minutes, and then blood will be available for transfusion.
  - If the antibody screen is positive, testing to identify the blood group antibody will be completed. The nurse and/or the ordering physician will be notified of the positive antibody screen and the delay in having compatible blood ready for the patient. It may take several hours to identify a difficult antibody. A minimum of 2 antigen-negative units will be identified, crossmatched and available. Notification of the nurse and/or physician will occur when antibody identity has been determined and compatible blood is available for transfusion.
  - NOTE: IT IS IMPORTANT TO HAVE THE TYPE AND ANTIBODY SCREEN COMPLETED PRIOR TO SURGERY.**
- **TYPE AND CROSSMATCH:** This is the test of choice, if the need for transfusion is certain or the chance of transfusion is highly likely. Testing is completed which includes, ABO, Rh antibody screen and crossmatch for the number of units ordered. Blood is available when the physician requests transfusion. Delays may occur if the patient has a positive antibody screen. The incompatibility must be identified and further testing completed to find compatible units. Notification of the patient's nurse and or physician, advising them of the problem and resolution, will occur initially and when blood is ready for transfusion.

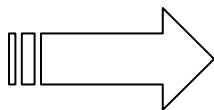


## New Test Methodology: Heparin Induced Thrombocytopenia (HIT) Antibodies

**Effective since: July 9, 2009**

Mercy Clinical Laboratory (MCL) is pleased to introduce a new method for the detection of heparin-induced thrombocytopenia (HIT) antibodies. This method utilizes a particle immunofiltration assay cartridge (PIFA®). An internal validation study demonstrated the PIFA method had similar sensitivity for the detection of Heparin/PF4 antibodies when compared to the current method, GTI-ELISA. Neither of these methods is regarded as having high specificity; therefore, any sample determined to be positive for Heparin /PF4 antibody by PIFA will be referred for confirmatory testing using the Serotonin Release Assay (SRA).

For questions on this test or other MCL services, please contact MCL Marketing at 515-247-4492.



Testing for Heparin/PF4 will be performed 24 hours a day, 7 days a week. The estimated turn around time will be approximately 3 hours. The required sample is fresh serum collected in a plain red top tube and received in the lab within 1 hour of collection. Gel serum separation tubes (SST) will not be accepted.

If the sample cannot be delivered to the lab within 1 hour of collection, follow the directions below.

- ◆ The specimen must be collected in a plain red top tube or a red top tube with clot activator. Do not use gel serum separator tubes (SST).
- ◆ The specimen must be allowed to clot 30 to 60 minutes before centrifugation.
- ◆ The serum should not be left on the clot for longer than 60 minutes after centrifugation or the PIFA test result may be invalid.
- ◆ Properly prepared serum that has been removed from the clot can be refrigerated for up to 72 hours.



**CLINICAL LABORATORY**

*A service of Mercy Medical Center—Des Moines*