MCL is now performing Quantiferon®-TB Gold Plus (QFT®-Plus) testing (4 tube collection) as of February 6, 2018. The previous generation of this test, Quantiferon-TB Gold® (3 tube collection), had been sent out to Mayo Medical Laboratory. Since the test is no longer transported to a reference laboratory, the turnaround time will be shortened.

Tuberculosis is a contagious bacterial infection spread primarily by coughing of patients with the active pulmonary form of the disease. In latent tuberculosis infection (LTBI), the bacterium infects a person but produces no symptoms unless it progresses to the active disease. On a global basis, approximately one out of three people is estimated to have latent TB infection and about 5-10% of those individuals, if left untreated, will progress to active tuberculosis. Screening of high risk individuals and treatment for LTBI play an important role in tuberculosis control efforts in the U.S. and around the world.

The QFT®-Plus test measures the cell-mediated immune response to a tuberculosis infection from both CD4+ and CD8+ T cells providing a broader assessment of TB infection. The previous generation test only tested the CD4+ response. Published studies underline the future potential of CD8+ T cells for distinguishing active from latent TB, discerning recent vs. old infections, detecting TB in certain populations such as HIV co-infection and young children, and assessing response to TB treatment. QFT®-Plus has a specificity of >97% and a sensitivity of >94%, producing more accurate results than the century-old tuberculin skin test. Interpretation and results should always include a risk assessment, radiography and other medical and diagnostic evaluations.

Instructions for collection must be followed to minimize indeterminate results. Collect 1 mL of blood into each of the 4 QFT®-Plus tubes. Volume of blood must be in the range of the black bar on each tube. Immediately after filling tubes, shake them 10 times just firmly enough to ensure the entire inner surface of the tube is coated with blood to solubilize antigens on tube walls. DO NOT CENTRIFUGE. All tubes must be labeled with last name, first name, date and time drawn.

Stability: Must be received by MCL within 12 hours of collection, room temperature.

Network hospital clients may need to process the tubes in their labs depending on their courier pick-up time. Instructions are as follows:

- The tubes must be incubated at 37o C. for 16-24 hours.
- Centrifuge tubes at 2000-3000 G for 15 minutes.
- Refrigerate.
- Once processed, specimens are good for 28 days.

MCL provides cards to put in the bio bag sleeve to clearly indicate that the tubes are refrigerated because already processed.

Additional testing for Tuberculosis

Coming soon to the Mercy Clinical Laboratory test menu is PCR detection of Mycobacteria tuberculosis complex from a sputum specimen. The Cepheid GeneXpert® MTB/RIF assay detects Mycobacteria tuberculosis complex and a mutation in the rpoB gene that is associated with resistance. Testing will be performed daily. By comparison, standard cultures can take 2-6 weeks for Mycobacteria to grow and conventional drug resistance tests can add weeks to the turnaround time.

Contact Jill Noble, Specialty Services Manager, at 515-247-4038 for additional information.
INFLUENZA IN IOWA

The graph below displays MCL influenza test volumes for the current season and last season. Influenza activity in Iowa continues to be elevated but it appears the peak of the season is over. Jeff Brock, an infectious disease pharmacy specialist at Mercy Medical Center-Des Moines said the flu season may have peaked, but it is nowhere near over. “It’s still going to be hanging around for a while,” Brock said. “We’re not out of the woods yet.” The dedicated efforts of MCL microbiology staff members are appreciated as they have been challenged by increased influenza testing volumes this season.

The number of Iowans hospitalized for complications of the flu is declining as are flu-related visits to clinics. Iowa has 185 confirmed deaths from flu complications this winter, about triple the number from a year ago.

BILE ACID SYNTHESIS, SERUM

Test ID: 7AC4

A blood test to screen for bile acid malabsorption is now available through Mercy Clinical Laboratory. Patients with increased bile acid in their stool suffer from chronic diarrhea termed bile acid diarrhea (BAD). This screening test requires a simple blood draw and is more palatable to patients than collecting a 48-hour stool sample for the 48-hour fecal bile acid test.

7 Alpha-hydroxy-4cholesten-3-one (7aC4) is an intermediate in the biosynthesis pathway of cholesterol to bile acids. Studies have shown that serum concentrations of 7aC4 are elevated in patients with BAD. A fasting morning serum sample should be collected. If results are positive, the confirmatory test (48-hour fecal bile acid test) may be ordered. Both tests are sent to Mayo Medical Laboratory. For more information, view the Webinar: “Testing Options for Patients with Chronic Diarrhea: A Focus on Bile Acid Malabsorption” at www.mayomedicallaboratories.com/edu.

To order, use the miscellaneous blood test and put in a comment “Bile Acid Synthesis, send to Mayo.”
WHAT IS PROFICIENCY TESTING?

Laboratory results play a major role in guiding clinical decisions. Beginning in 1994, clinical laboratories performing non-waived testing were required by the Clinical Laboratory Improvement Amendments (CLIA) to enroll and participate in a Proficiency Testing (PT) program approved by the Centers for Medicare & Medicaid Services (CMS). Successful PT performance is a requirement for maintaining CLIA certification to perform testing for certain analytes. Most laboratory professionals are well-versed in this required element of running a successful laboratory.

PT is the testing of unknown samples sent to a laboratory by an approved PT program. It provides an external, unbiased assessment of laboratory performance. The laboratory performs testing on the samples, treating them the same as a patient sample. Results are sent back to the PT program within the timeframe allowed by the program. The PT program grades the results and sends the laboratory its scores, which are monitored by CMS and accreditation organizations.

A detailed list of CMS approved PT programs is available on the CLIA website: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. PT is required for regulated, non-waived tests. A listing of regulated analytes can be found on the CLIA website listed above or from your PT provider. PT is not required for waived testing, but many laboratories choose to enroll waived tests to verify the accuracy and reliability of testing including staff competency.

PT results must be reviewed by laboratory staff and the laboratory director. If the score is less than 100 percent, an investigation is done to determine why results were outside of the acceptable range. When the cause of the error is determined, corrective action is documented. An unsuccessful PT performance (score of less than 80 percent) may require technical assistance and training. Serious sanctions may be implemented, such as no longer being able to perform the failed testing until corrections are completed.

Communication with another laboratory about PT results and referring PT samples to another laboratory to be analyzed have always been forbidden under CLIA. Consequences for a laboratory doing either of those things prior to the cut-off date for submitting results may include the loss of CLIA certification for a year and barring the laboratory director from owning or directing a laboratory for up to two years. A laboratory that receives PT samples from another laboratory and is requested to perform testing on them must NOT perform the testing and MUST notify the CMS Regional Office at 877-267-2323 as soon as possible.

Mercy Clinical Laboratory participates in proficiency testing for a large group of regulated tests performed in its laboratory. For the year 2017, MCL reported more than 3500 proficiency testing results, with 99.2 percent within acceptable ranges. For comparison, a similar group of laboratories had a combined acceptable score of 98 percent. MCL is committed to quality and this is one way we assure quality in laboratory testing.

FOR MORE INFORMATION on how to meet the requirements of Proficiency Testing, refer to the CLIA brochure found on the CLIA website www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html.

LAB STAFF SPOTLIGHT

Cait Galvin has joined our lab team as the new 2nd/3rd shift Specimen Management Supervisor. Cait received her Associates in Health Care Administration from Iowa Central Community College. She came to us after working as a supervisor at Biolife for the past 3 years, where she focused on having the proper coverage and workflow in her area, ensuring high levels of customer service and satisfaction, and training new employees. Cait lives in Ames with her dog and cat and enjoys reading, traveling, and eating.
MCL PATIENT SERVICE CENTERS

MCL patient service centers provide prompt, quality service at the locations listed below. For a basic blood draw, please utilize one of our three conveniently located patient service centers.

**Mercy Medical Plaza - Atrium**
411 Laurel St., Level A, Ste. 265, Des Moines
Phone: (515) 643-8924  Fax: (515) 643-8239
Hours: Monday – Friday, 6 a.m. to 5 p.m.

**Mercy West**
1601 NW 114th St., Ste. 134, Clive
Phone: (515) 222-7500  Fax: (515) 222-7510
Hours: Monday – Friday, 7 a.m. to 5 p.m.

**Mercy North**
800 E. First St., Ste. 1400, Ankeny
Phone: (515) 643-7710  Fax: (515) 643-8176
Hours: Monday – Friday, 7 a.m. to 4 p.m. (Closed noon - 1 p.m. for lunch)

MCL PHOTO SPOTLIGHT

Pictured are some of our experienced phlebotomists who staff the MCL Patient Service Centers.

REMINDERS...

- Mercy Clinical Laboratory will be transitioning Clostridium difficile testing to the GeneXpert® platform on March 27, 2018. This move will decrease turnaround time and allow longer stability of unpreserved stool samples including 24 hours at room temperature and 5 days at refrigerator temperature. Samples in Cary Blair transport media will be rejected; the only acceptable specimen type is an unpreserved stool specimen. The ordering process and pricing remain the same.

- Please do not place labels with barcodes on the test requisitions. If these labels are on the requisition, we have to black out the barcode so it is not read by our scanner when the paperwork is scanned into our system.

- A genital culture cannot be performed from the Cobas® transport tube which is for Chlamydia and Gonorrhea PCR testing. Please collect a separate culturette swab or ESwab for genital cultures. Remember to put the label for CTNG testing on the Cobas® transport tube or PAP vial, and the label for the genital culture on the swab. This will help us process the samples more efficiently.