

Laboratory Communiqué

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The Laboratory Communiqué is a quarterly publication released by Billings Clinic Laboratory Services as an informational tool for medical staff and laboratorians.

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Test Changes

H. pylori, IgG ELISA

In an effort to follow current Helicobacter pylori guidelines and to continue providing quality laboratory testing for our clients, on March 23, 2016, we discontinued our Helicobacter pylori IgG Antibody Serum test, test code #7010.

The American College of Gastroenterology and the American Gastroenterological Association recommend that serologic testing for H. pylori be avoided as a means of diagnosis of active H. pylori infections due to the following limitations:

- ✓ Poor performance characteristics of these assays compared to alternative testing.
- Serologic testing cannot be used to distinguish active from past infection or to document.
- C Eradication of the organism following successful treatment.
- ✓ Lack of reimbursement from and increasing number of insurance providers.

Recommendations are to replace serologic testing with stool antigen testing. We are currently sending Helicobacter pylori Antigen Feces testing to Mayo Medical Laboratories (MML) and will continue to do so until we bring this test in-house. An implementation plan is being put in place and we hope to bring Helicobacter pylori Antigen Feces testing live at Billings Clinic this summer. In the meantime, please order Helicobacter pylori Antigen Feces.

- Test Code: 7142
- CPT code: 87338
- Specimen Requirements: Minimum volume of 5 grams feces placed in a plastic stool container and stored at frozen temperature.

Leukocyte Alkaline Phosphatase Stain (LAP)

Effective April 4, 2016, Billings Clinic Lab discontinued the Leukocyte Alkaline Phosphatase (LAP) stain. For evaluation of a possible myeloproliferative disorder in a patient with unexplained leukocytosis and/or splenomegaly, BCR-ABL or JAK2 testing are recommended depending on the clinical scenario. These tests are available through the laboratory as mail out tests to Genoptix Medical Laboratory.

Test Reference Range Updates

ALT (SGPT) Reference Range Updated

The Reference Range for both male and female from 15 years to150 years was updated.

Old Range: 0 - 48 IU/L New Range: 0 - 55 IU/L

Direct Bilirubin Reference Range Updated

The Reference Range for both male and female from 17 years to150 years was updated.

Old Range: 0.0 – 0.3 mg/dL New Range: 0.0 – 0.5 mg/dL

Test Clarification

Antiphospholipid Syndrome Panel Test Code #2081

Phospholipid Antibody Panel (Cardiolipin Panel) Test Code #2068

Lupus Anticoagulant Panel Test Code #2079

Lab Week

April 24-30

Test/Panel Clarification

Frequently we have tests included in the Phospholipid Antibody Panel (Cardiolipin Antibody Panel), ordered with the panel. In order to prevent duplicate charges and to maintain compliance with billing regulations, the duplicate tests are cancelled. Clarification of the tests in each panel may be helpful for ordering purposes.

We currently have the following three panels that can be ordered as an aid in the diagnosis of Antiphospholipid Syndrome (APS) and Lupus Anticoagulants (LA).

Antiphospholipid Syndrome Panel Test 2081

This is our all-inclusive panel which is useful for identifying and distinguishing lupus anticoagulants from anticardiolipin antibodies. This larger panel includes the following two smaller panels:

- 1. Lupus Anticoagulant Panel
- 2. Phospholipid Antibody Panel

Phospholipid Antibody Panel (Cardiolipin Antibody Panel) Test 2068

This panel is performed on serum and includes ELISA testing for:

- ✓ anti-Cardiolipin, IgG (ACL, IgG)
- ✓ anti-Cardiolipin, IgM (ACL, IgM)
- ✓ Beta-2 Glycoprotein-1, IgG antibody (B-2GP-1, IgG)
- ✓ anti-Phosphatidylserine IgG (aPTS, IgG)
- ✓ anti-Phosphatidylserine IgM (aPTS, IgM)

Lupus Anticoagulant Panel

Test 2079

This panel is performed on citrated plasma and is built to reflex to additional testing if indicated.

- ✓ DRVVT Screen is initially performed and if prolonged, additional testing may be:
- ✓ DRVVT Confirmation
- ✓ DRVVT Mixing Study 1:1
- ✓ DRVVT Confirmation Mixing Study 1:1

Lab Week

Medical Laboratory Professionals Week is April 24-30. This is our opportunity to increase the understanding of and appreciation for our clinical laboratory personnel. In our laboratory we have an array of professional and support staff. To provide an understanding of the different professional staff, let's start at the top and identify who they are.

Pathologists are physicians who study and diagnose disease and are usually either clinical or anatomical pathologists. Anatomical pathologists analyze samples of tissue and cells to aid in determining the diagnosis and cause of diseases and how serious or advanced a disease might be. Their education requires a baccalaureate degree, medical school and a residency. Pathologists who wish to specialize in areas such as dermopathology, surgical pathology or pediatric pathology need to complete a fellowship. These programs last a year or two and provide more narrowly focused training than do residencies.

The medical director of our laboratory is a pathologist and each of our laboratory departments has a pathologist overseeing the operation of that department. Our pathologists also serve as medical directors for outreach laboratories and provide them leadership support.

Pathology Assistants (PA) are highly trained allied health professionals who provide various services under the direction and supervision of pathologists. They are responsible for the gross examination and dissection of anatomic pathology specimens and prepare the tissues which will be processed by the histotechnologists and histotechnicians for

Automation Updates

Blood Bank

Grifols ERYTRA

Chemistry

Siemens Chemistry Vistas and Centaur with full Track and Automation examination by the pathologists. A Pathologists' Assistant will have a baccalaureate degree from a regionally accredited college/university and successful completion of a NAACLS accredited PA program.

Histotechnologists and Histotechnicians are specially trained professionals who prepare and process surgical and autopsy specimens by preparing tissue slices which are mounted on slides. The slides are then stained with special dyes or treated with chemicals to reveal specific structural and cellular details for microscopic analysis by the pathologist. **Histologists (HTL)** have a baccalaureate degree from a regionally accepted college/university and successful completion of a NAACLS accredited program or one year full time acceptable experience in a histopathology laboratory. **Histotechnicians (HT)** have successfully completed a NAACLS accredited Histotechnician program or obtained an associate degree from a regionally accepted college/university and completed one year of histopathology clinical work at an accredited laboratory.

Cytotechnologists are clinical laboratory scientists who specialize in detecting the presence or absence of disease at the cellular level. They work in collaboration with pathologists to diagnose benign and infectious processes, cancerous and precancerous lesions and malignant disease. The most notable test performed is the Pap smear but there are also specimens from many other sites that require cytological examination. A Cytotechnologist will have a baccalaureate degree or higher from a regionally accredited college/university and successful completion of a CAAHEP accredited Cytotechnology program.

Medical Technologists or Medical Laboratory Scientists perform the same role, undergo the same training and require the same licensing. The difference between them is purely one of terminology and credentialing organizations. They must earn a baccalaureate degree from a regionally accredited college/university and an internship of clinical rotations in a working lab. They are certified as MT (ASCP), MLS (ASCP)^{CM} or MT (AMT). They are highly trained professionals who use sophisticated instrumentation and manual techniques to analyze blood, urine, feces, and body fluids. They also identify infective microorganisms, crossmatch blood for transfusions and oversee Point of Care Testing. Laboratory departments include: Blood Bank, Hematology, Coagulation, Microbiology, Serology, Chemistry, Molecular and Point of Care.

Medical Laboratory Technicians (MLT) have an associate degree from a recognized college/university and successful completion of a NAACLS or ABHES accredited MLT program. Other eligibility routes may be an associate degree and a prior CLA (ASCP) certification, an associate degree and U.S. military laboratory training or finally an associate degree and three years of full time acceptable clinical laboratory experience. MLTs can perform many of the same tasks as a MT or MLS except for those more complex procedures requiring more expertise or education.

Lab Technical Assistants are trained on-site or have previous health care experience. They assist the technologist and technicians within the various clinical laboratory departments with their daily workload and can perform waived laboratory testing and analytical set-up.

Phlebotomists are trained and qualified to collect blood specimens for the laboratory by venipuncture or capillary puncture. They select the appropriate equipment and technique based on a thorough understanding of the anatomy and physiology of the patient. They have the most contact with patients and medical staff and are our first line representatives of the laboratory. Certification is strongly recommended for our phlebotomy staff. To be eligible for the ASCP examination, in addition to a high school graduation or equivalent, one must have completed an approved phlebotomy program or completed one year full time acceptable experience as a phlebotomist in an accredited laboratory or completed another accepted allied health professional/occupational education as indicated by ASCP.

Support Staff are many and their jobs vary by assignment. We have central processing staff that receive and process specimens from the in-house and clinic blood draws and also from our satellite labs and outreach clients. We have customer service staff that provide excellent support for billing and test questions and answer approximately 200 phone calls a day. Pathology secretaries transcribe and process histology/pathology reports. LIS staff provides us comprehensive computer support and the marketing staff promotes our laboratory services and supports our reference clients. The support staff, just by the definition of the word is the backbone of our laboratory!



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Automation Updates

The Grifols ERYTA has been set up, validations performed and test correlations are well underway. Primary user training for our Blood Bank Department Lead and Blood Bank Med Tech Level II was completed in February during an intensive week of training at the Grifols training site in Emeryville, CA. Staff training was recently completed on-site and the Blood Bank staff is eager to start using the instrument. The tentative Go-Live date is early May.



Chemistry

Blood Bank

The Chemistry Department will be replacing their current Abbott Instruments and APS (automatic processing system) with a similar Siemens System. The Siemens Vistas, Centaur and Aptio track/automation system will provide many benefits over the current system such as:

- Improvements in sample size for neonates and pediatric patients
- ✓ Improved Turn-Around-Times for some assays
- Consolidation of testing platforms
- Improved on-board reagent capacity
- ✓ Increased test redundancy
- ✓ Automated specimen aliquoting for send-outs and esoteric tests
- ✓ Increased capacity for centrifugation with the addition of a 2nd centrifuge
- ✓ Post analytical specimen storage-on-line

Plans are underway for the lab remodel which will install the chemistry instruments, track and automation to a different area of the lab. A Go-Live is tentatively planned for July.

For more information about Billings Clinic Laboratory please call (406) 657-4060. www.billingsclinic.com.

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