

WINTER 2017

Lab Link

THE NEWSLETTER OF MAIN LINE HEALTH LABORATORIES



UPDATE

QuantiFERON-TB Gold

QuantiFERON®-TB Gold, an Interferon-gamma release assay (IGRA), was developed to aid in the diagnosis of *Mycobacterium tuberculosis* infection and to address limitations of century-old tuberculin skin test (TST) or purified protein derivative (PPD) skin test. QuantiFERON-TB Gold blood test is as sensitive as the PPD skin test, but it yields fewer false positive results, and does not require the patient to return as the skin test does.

The QuantiFERON-TB assay is a qualitative test of infection. It measures the production of interferon-gamma by effector T-cells in response to TB peptide antigens. Effector T-cells are considered to be present only during current infection, but not in old or cured infection. A positive result suggests that current *M. tuberculosis* infection is likely, whether active disease or latent TB infection. A negative result suggests that *M. tuberculosis* is unlikely but cannot be totally excluded, especially when the illness is consistent with tuberculosis or the likelihood of progression to disease is increased (e.g. because of immune suppression). In rare cases results cannot be interpreted, as the blood cells have not responded to a positive control stimulant. These results are called "indeterminate"; TB infection can neither be excluded nor confirmed.

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New Main Line Health Lab Opens in Concordville



In December, Main Line Health Laboratories opened a patient service center in the Main Line Health Center in Concordville. The Lab hours are very convenient—open 7 days a week (see below). The experienced phlebotomy staff is gentle and skilled with patients of all ages.

The facility also has a health club with aquatics and full service radiology and imaging. The Concordville Health Center is easily accessible via Route 202 and Route 322. Ample free parking is available. In addition, SEPTA's 111 bus route stops within a block of our office.

MAIN LINE HEALTH CENTER
1020 BALTIMORE PIKE | SUITE 100
GLEN MILLS, PA 19342
TEL: 484.227.7777 | FAX: 484.227.7898

HOURS:
MONDAY-FRIDAY: 7:00 AM-7:00 PM
SATURDAY: 7:00 AM-1:00 PM
SUNDAY: 9:00 AM-2:00 PM
CLOSED HOLIDAYS

Most major insurances are accepted. Patients with Aetna HMO plans can also have specimens collected at the facility. A list of in-network insurance plans can be obtained by calling Jack Galamb at 484.580.4006. Turnaround time for most tests is within 24 hours. Stat testing should be referred to Riddle Hospital or one of the other Main Line Health hospital labs. If you have any questions, please call the site Manager, Judy Smith, at 484.227.3221. ■



New Assay For Heparin-Induced Thrombocytopenia (HIT)

Effective February, Main Line Health Laboratories will begin to offer the **Heparin-Induced Platelet Antibody EIA with reflex to Serotonin Release Assay (PF4G)**. This assay replaces the current method of screening for Heparin-Induced Antibody (HPF4R) by Particle Immuno-Filtration Assay (PIFA).

Heparin PF4 by PIFA testing is known to have significantly high false positive results as well as false negative results for the diagnosis of heparin-induced thrombocytopenia. The Immucor (Genetic Testing Institute Diagnostics) ELISA Assay is a better assay which we have found to have a 96.7% agreement with the Serotonin Release Assay. In addition, a recent study found Immucor ELISA assays to have an overall sensitivity of >95% and specificity of >90%.¹ Laboratory testing for heparin-induced thrombocytopenia will be available to order as PF4G with reflex to Serotonin Release Assay, PF4G with no reflex (PF4GN), and Serotonin Release Assay (SRA).

Heparin-Induced Platelet Ab EIA w/ reflex Serotonin Release Assay should be utilized in patients with an intermediate or high pre-test probability of having Type II HIT as determined by a validated scoring tool such as the "4 T's score." Each time a Heparin-Induced Platelet Ab EIA w/reflex Serotonin Release Assay test is ordered in the SmartChart or EPIC system, a 4 T's score calculator prompt will appear. This module must be completed and the computed score will characterize the patient as low-, intermediate-, or high-risk for having HIT. There will be a suggestion to reconsider ordering this test if the 4 T score falls into the low probability range.

Please forward any questions you may have to Dr. Pradeep Bhagat, Medical Director, Main Line Health Laboratories, at 484.476.3521, or BhagatP@mlhs.org. ■

¹Nagler M, Bachmann LM, Cate HT, Cate-Hoek A. *Diagnostic value of immunoassays for heparin-induced thrombocytopenia: a systematic review and meta-analysis*. Blood 2016 Feb 4 Vol 127:546-557

Providing Clinical Information with Cervicovaginal Cytology

Why It's Important

Like any other laboratory test, cervicovaginal cytology is best interpreted in light of pertinent clinical history.

CLIA '88 amendments require in Section 493.1241-Standard: Test Request, that Pap test requisitions must solicit the patient's last menstrual period (LMP), age or date of birth, notation of previous abnormal diagnoses, treatment or biopsy, and additional pertinent information.

Clinical information sections on MLH Cytology requisition forms have not been utilized or have been underutilized. Approximately 30% of all cervicovaginal cytology tests received by the Main Line Health Cytology Laboratory from January to October 2016 had insufficient or no clinical information for both electronic and handwritten requisition forms.

Why is clinical information so important?

First, only previous diagnoses rendered at MLH are available to cytotechnologists and pathologists via our electronic medical records. The clinician and the information provided on the requisition form may be the only common link the MLH laboratory has to this valuable patient history.

Additionally, this information helps the cytotechnologist or pathologist to more precisely interpret certain findings on a Pap test. For instance, if the patient's history is abnormal, the Pap

test must follow a quality control path where it is screened a second time by a senior cytotechnologist. If last menstrual period (LMP) is not provided, it cannot be determined whether endometrial cells are in cycle or if they are an abnormal finding. Sending the Pap test to a pathologist for final sign out may be avoidable if menstrual history is provided.

Identifying patients on hormone replacement therapy can explain elevated estrogen effect in post-menopausal patients.

Providing this information can prevent unnecessary testing, improve turnaround time, and save additional fees.

We are appealing to you to provide complete patient history information on the requisition form. In doing so, we will all be able to provide superior patient care. If you have any questions, please contact Kim Bianco, Cytology Supervisor, at 484.476.8418, BiancoK@mlhs.org. ■



QuantiFERON-TB Gold

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There are 3 reasons why a QuantiFERON-TB test result could be indeterminate (Ref):

1. There is a problem with specimen collection and handling
2. The person is immunocompromised
3. Delayed incubation

Sample collection is a critical part of Tuberculosis blood testing. There are several steps that require strict attention to detail to produce a valid qualitative result:

1. If a phlebotomist is using a butterfly needle, blood collection must be preceded by a discard tube.
2. QuantiFERON-TB Gold (QFT) collection tubes (3 in a package) require 1 mL of blood in each tube. There is an indicator on the tube (a black dash) which serves as a “fill” line. These tubes fill more slowly than tubes for other blood tests.
3. These special collection tubes are coated with antigens with which the blood must be thoroughly mixed. This step is so important—giving all three tubes 10 firm shakes to ensure that the blood comes in contact with the entire interior of these special tubes.
4. Samples must be placed in a 37°C incubator within 16 hours of collection, either at the draw site, or they must be promptly delivered to the Main Line Health laboratory.

The “indeterminate” finding should be a rare event—<3% of total test findings.

Assisted by Cellestis representatives (the manufacturers of the QuantiFERON-TB Gold Test System), MLHL has made great strides in educating staff who perform phlebotomy on the proper procedure for drawing blood for tuberculosis testing. MLHL closely monitors the number of patient samples that yield an indeterminate result and found that these educational efforts have lowered the rate of patient samples whose results are indeterminate to be below the recommended threshold at 1.73%.

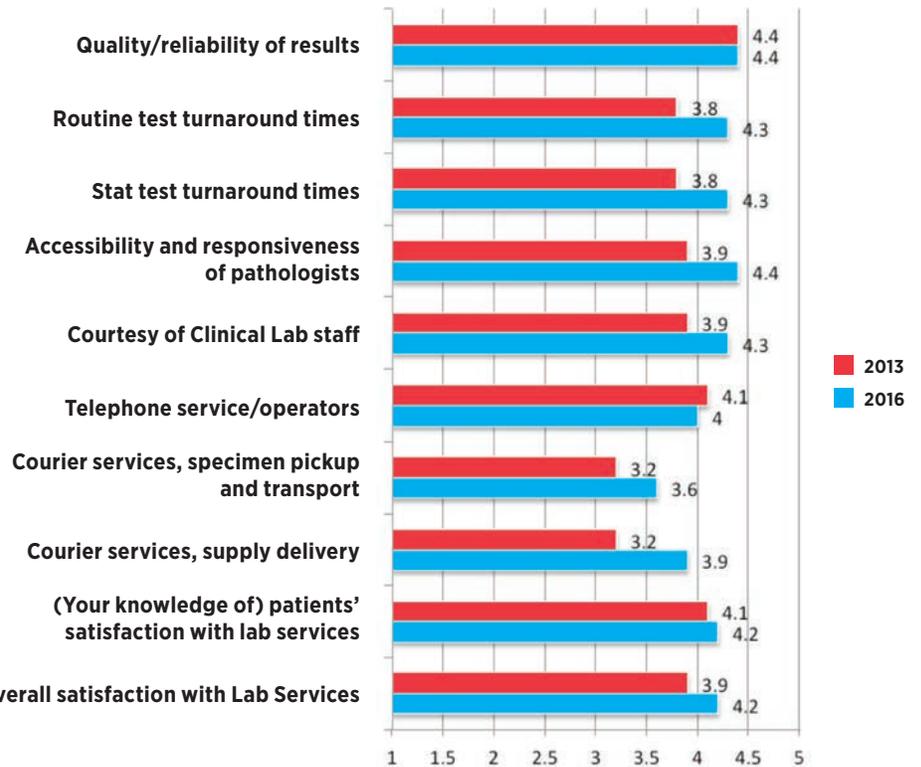
Please forward any questions you may have to Dr. Pradeep Bhagat, Medical Director, Main Line Health Laboratories, at 484.476.3521, BhagatP@mlhs.org, or to Annemarie Brewer, Immunology Supervisor, at 484.476.8408, BrewerA@mlhs.org. ■

Ref: <http://ofid.oxfordjournals.org/content/1/2/ofu088.full>

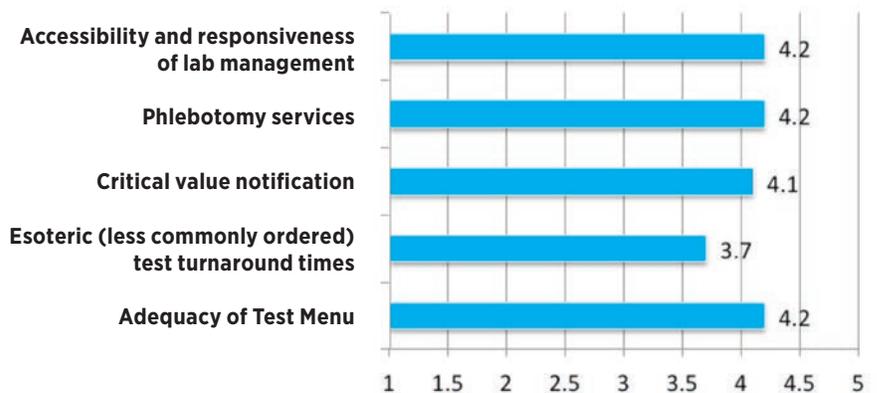
Lab Survey Results

We thank all who participated in the recent Main Line Health Laboratory Satisfaction Survey. 166 responses were received. Surveys were sent out to the medical staff, office managers and long term care administrators. You were asked to rate the lab in specific categories. The ratings correspond to a numerical score as follows:

Poor	Below Average	Average	Above Average	Excellent
1	2	3	4	5



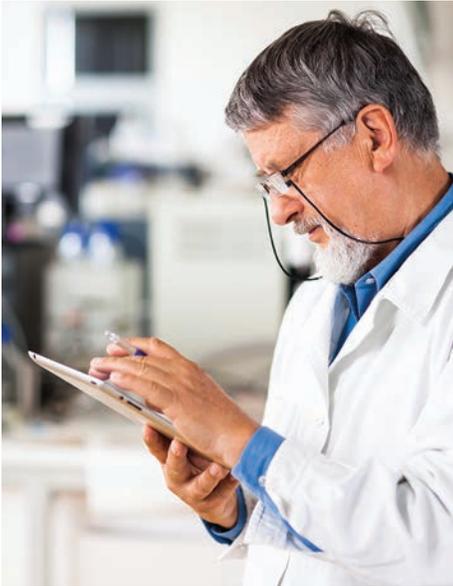
The results from 2016 show a significant improvement over 2013 in almost all categories except Quality/reliability of results, which was the same at 4.4 (above average to excellent) and Telephone service, which dipped slightly from 4.1 to 4.0. Also in 2016, several categories were added. Those categories' scores are shown in the chart below:



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Lab Survey Results

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The final question asked if you would recommend Main Line Health Laboratories to another physician. 73 percent said “yes”, 4 percent said “no” and 23 percent “not sure”. You could also add comments and optionally identify your practice or facility. We especially thank those who identified themselves so the client service team can follow up and address specific concerns.

While we are encouraged by these results, your feedback has identified potential areas of improvement. We at MLHL are continually working to improve quality of service and patient safety. Your participation helps our effort to achieve those goals.

If you have any questions, contact Pradeep Bhagat, MD, Medical Director, at 484.476.3521. If you have a specific issue or concern, please contact Jack Galamb, Outreach Manager at 484.580.4006. ■

Coagulation Testing Update

Main Line Health Laboratory offers a range of tests helpful in the evaluation of patients with thromboembolic or bleeding disorders.

The test menu includes basic coagulation tests such as PT, PTT, thrombin time, fibrinogen, D-Dimer, and Platelet count with Immature Platelet Fraction, which are available at all MLH hospital laboratories.

For patients presenting with bleeding and/or a prolonged coagulation screening test, the Core laboratory at Lankenau Medical Center offers more complex testing such as the “Prolonged PT/PTT workup” which includes an evaluation of abnormal coagulation values in a systematic fashion following an algorithm developed by the laboratory, based on published literature (*An Algorithmic Approach to Hemostasis Testing, Kandace Kotke Marchant, CAP Press 2008*). The array of available testing includes mixing studies, factor assays, inhibitor studies, as well as the quantifying of Factor VIII specific inhibitor in Bethesda units.

For Patients with thrombophilia (hypercoagulability), Main Line Health Lab offers the following:

- Assays for Protein S, C, and Antithrombin III (naturally occurring anticoagulants) PCR testing for Factor 5 Leiden and Prothrombin Gene Mutation
- Homocysteine and Factor VIII assays
- Lupus Inhibitor screening

Note: Prolonged PT/PTT Workup and Inhibitor studies, including evaluation for Lupus Anticoagulant, are interpreted by the pathologist.

In order to determine the optimal approach to the evaluation of a coagulation disorder, a discussion of the clinical situation with the pathologist is highly recommended.

Specimen requirements for Coagulation testing are as follows:

- Routine Coagulation testing (PT, PTT, Fibrinogen, D-Dimer): one Na Citrate (blue top) tube
- Factor assays, Mixing studies: one Na Citrate (blue top) tube
- Prolonged PT/PTT workup or Lupus Anticoagulant: three Na Citrate (blue top) tubes
- Thrombophilia Workup (Protein S, C, AT3): two Na Citrate (blue top) tubes

Note: Certain coagulation tests such as factor assays, prolonged PT/PTT workups, inhibitor assays, and Bethesda units are labor intensive and are offered during the first shift only. If clinically indicated, however, and after discussion with the pathologist, these tests can be performed on an as needed basis as time and staffing allow.

For questions regarding coagulation issues please contact: Dr. Vlasta Zemba-Palko at 484.476.2608 or Laura O’Shea, Hematology Supervisor, at 484.476.2738. ■



Main Line Health Laboratories Contact Information

Client Services 484.580.4200

Main Line Health Laboratories Billing 484.829.6060

Main Line Pathology Associates Billing 610.459.3113

Pradeep Bhagat, MD, Medical Director, Main Line Health Laboratories 484.476.3521

Judyann Gilbert, System Director, Main Line Health Laboratories 484.476.2630

Rowena Burrows, Division Manager, Core Laboratories, Lankenau 484.476.2610

Liz Hallinan, Rapid Response Lab Manager, Paoli 484.565.1412

Judy Smith, Rapid Response Lab Manager, Riddle 484.227.3221

Erin Tretter, Rapid Response Lab Manager, Bryn Mawr 484.337.3545

Jack Galamb, Manager, Outreach 484.580.4006



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