Tuberculosis, an infectious disease caused by *Mycobacterium tuberculosis*, has been an important human disease throughout recorded history and continues to be a significant cause of infection throughout the world today.

In 2009, the World Health Organization estimated that over one third of the world’s population or two billion persons are infected with *M. tuberculosis*. Of these infected individuals, approximately 9 million develop active tuberculosis each year who serve as an infectious reservoir of disease transmission to uninfected individuals. Fortunately, the great majority of people infected with *M. tuberculosis* have latent infection, do not manifest overt symptoms of disease, and are not infectious.

However, the two billion persons worldwide who have latent or asymptomatic *M. tuberculosis* infection can develop active disease any time during their lifetime and become infectious. As such, individuals should be screened periodically to determine whether they have been exposed recently to *M. tuberculosis* and have latent or asymptomatic infection.

For over a century, the tuberculin skin test (TST) was the only immunologic test approved for use in the United States to screen for tuberculosis infection. The TST, also known as the PPD skin test, measures cell-mediated immune responses to tuberculin PPD which is made up of a multitude of mycobacterial proteins, most of which are present in the TB vaccine, Bacille Calmette-Guerin (BCG), and is shared with many other environmental mycobacteria.

Because of this, there are limitations in the use of the TST that could lead to incorrect diagnosis. Some of these limitations involved false positive results that may be due to cross-reactivity with prior BCG vaccination or exposure to environmental mycobacteria, false negative results in anergic or immunocompromised individuals, and/or the subjective bias associated with skin test interpretation. Despite these limitations, the TST was used for over 100 years because it was the only screening test available.

In 2001, recognition that interferon gamma plays a critical role in regulating cell-mediated immune responses to *M. tuberculosis* infection led to the development and eventual FDA-approval of interferon gamma release assays (IGRAs) for the detection of active and latent *M. tuberculosis* infections. Several improved generations of IGRAs have been developed over the last decade, the most recent being the QuantiFERON-TB Gold In-Tube assay.

Because each new generation of IGRAs offers advantages over the previous one, the CDC publishes new guidelines for the IGRA recommended use, particularly as more scientific studies are published on the reliability of the test. The most recent CDC guideline entitled “Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection - United States, 2010” was published in the June 25, 2010 issue of *Morbidity and Mortality Weekly Report*. Readers are referred to that publication for the specific recommendations detailed in those guidelines (www.cdc.gov/mmwr).

The 2010 CDC guidelines supersede previously published recommendation for the use of IGRAs. In short, the new guideline recommends that either TST or IGRAs may be used in diagnosing *M. tuberculosis* and cites the advantages and disadvantages of each test infection. These tests may be used for surveillance purposes and to identify patients most likely to benefit from treatment.

The CDC document also addresses multiple recommendations regarding test selection and medical management after testing.

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**New CDC Test Guidelines for Detecting *Mycobacterium tuberculosis* Infections Using Interferon Gamma Release Assays**

By Paul A. Granato, Ph.D., Director of Microbiology

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www.laboratoryalliance.com
Laboratory Alliance Earns Gold Seal of Approval

The anatomical and clinical laboratories at Laboratory Alliance were awarded accreditation by The Joint Commission (TJC) through March 2012. By demonstrating compliance with TJC’s national standards for health care quality and safety, Laboratory Alliance has earned the commission’s Gold Seal of Approval.

This follows an unannounced, on-site evaluation on Feb. 8-12 at our central laboratory on Electronics Parkway in Salina, N.Y., the corporate office on Buckley Road in Syracuse, N.Y., our three rapid response laboratories at Syracuse hospitals, and at some of our 12 patient service centers.

The accreditation award recognizes Laboratory Alliance’s dedication to complying with TJC’s state-of-the-art standards on a continuous basis.

“We continually strive to improve the quality of our services, and meeting The Joint Commission’s rigorous national standards is an important recognition of our efforts,” said Anne Marie Mullin, vice president of business development and marketing.

TJC evaluated the laboratory’s performance in complying with nearly 300 standards related to quality control, safety, infection control, leadership, management of human resources, management of information, ongoing performance improvement activities and other issues.

“The facility does not receive advance notice of the inspection dates when a team of surveyors arrives and a thorough survey is conducted in every department at all of our locations,” said Mullin. Since beginning operations in 1998, Laboratory Alliance has been subject to a full-scale inspection every year. During the year that falls between TJC inspections, the facilities are inspected by the New York State Department of Health (NYS-DOH) Clinical Laboratory Evaluation Program.

TJC evaluates and accredits more than 15,000 health care organizations and programs in the United States, including more than 8,000 hospitals and home care organizations, and more than 6,800 other health care organizations that provide long term care, assisted living, behavioral health care, laboratory and ambulatory care services.

An independent, not-for-profit organization, TJC is the nation’s oldest and largest standards-setting and accrediting body in health care.

New CDC Test Guidelines for Detecting *M. tuberculosis* Infections

Continued from page 1

Importantly, the new CDC guidelines recommend the preferred use of the IGRA test over the TST particularly in BCG vaccinated individuals and those patients who are not likely to return for follow-up reading of the TST.

Laboratory Alliance’s Microbiology Department has been offering the QuantiFERON-TB Gold In-Tube test since its release in 2008. The QuantiFERON-TB Gold In-Tube test offers increased sensitivity because it tests for three mycobacterial protein antigens rather than two used in the earlier generation of this assay. The specifics of the current assay are briefly described as follows.

All IGRAs are based upon the cell-mediated immune response (CMI) following *M. tuberculosis* infection that results in sensitization of T-cell lymphocytes specific to *M. tuberculosis* antigens. Gamma interferon (IFN) is a protein produced by sensitized T-cells (primarily CD4+ but also CD8+) upon stimulation with their specific antigen.

The QuantiFERON-TB Gold In-Tube assay detects CMI responses to tuberculosis infection by measuring IFN produced in whole blood after incubation with synthetic peptides of the *M. tuberculosis* antigens ESAT-6, CFP-10, and TB7.7. These TB specific proteins, which are secreted by *M. tuberculosis*, stimulate a robust and detectable CMI response in infected people. They have been demonstrated to be both specific for *M. tuberculosis* infection, unaffected by BCG vaccination status and most nontuberculous mycobacteria.

Response to either ESAT-6, CFP-10, or TBT7.7 antigen indicates infection. The antigens are small proteins (<10Kd) with a limited number of epitopes, so although the majority of tuberculosis infected individuals respond to all three antigens, many infected individuals may respond to only one. Unlike skin testing, there is no stratification of the diagnostic cut-off based on patient history, BCG vaccination status or risk factors, and thus the answer in most cases, is a simple yes/no to TB infection.

The QuantiFERON-TB Gold In-Tube test is intended for use only with blood specimens collected into three special tubes for this test. We strongly encourage the collection of all specimens by 2:00 p.m. Monday through Friday, in order to ensure that they are received in the Microbiology Department no later than 5:00 p.m. to initiate T-cell activation. These activated specimens are tested on Wednesday and Thursday.

Health care providers who want to order this test on their patients should contact the Laboratory Alliance Customer Service Department at (315) 461-3008 to schedule this test.
Healthcare Community Launches HealtheConnections

Laboratory Alliance executives joined other members of the Central New York health care community and members of the media at a press conference on June 28 to announce the launch of HealtheConnections, a Central New York regional health information organization (RHIO) and electronic health information exchange.

The conference was sponsored by the Health Advancement Collaborative of Central New York (HAC-CNY), a collaboration of leaders from the hospital, physician, business, insurance, and consumer sectors with a mission to improve health care quality and control costs in our region.

Congressman Daniel Maffei was recognized for securing $900,000 in federal funds to support this critical initiative and attendees were thanked for their support in HAC-CNY’s award of $2.1 million from New York state.

Featured speakers included Congressman Maffei; Deputy Commissioner Rachel Block, State of New York Department of Health, Office of Health Care Transformation; and HAC-CNY President Orrin B. MacMurray, chairman of C&S Companies. The press conference was held at C&S Companies in North Syracuse.

To learn more, go to http://hac-cny.org.

Li Chen Represents Laboratory Alliance at Microbiology Conference

Medical Technologist Li Chen, who works in our Microbiology Department, attended the 110th General Meeting of the American Society of Microbiology held May 23-27 in San Diego along with Director of Microbiology Paul A. Granato, Ph.D.

They presented the clinical poster (seen left) about Campylobacter Enteric Infections that is based on testing that we performed.

At the meeting, the scientific program featured nearly 300 individual colloquia, symposia, roundtable discussions, award lectures and poster sessions.

Annual Blood Drive at Laboratory Alliance on Aug. 18

A Red Cross Blood Drive will be held in our Conference Room at the Corporate Offices on Wednesday, Aug. 18. The address is 1304 Buckley Road, suite 300.

Sponsored by Laboratory Alliance and Nephrology Associates, appointments will be scheduled from 9 a.m.-2 p.m. by contacting Marsha at (315) 461-5903 or by e-mail to marshaherbst@lacny.com

August Netbook-A-Day Giveaway

As summer winds down and you prepare to get back in your routine we want to help you get reconnected!

Donate blood in August and be eligible to enter for a chance to win an Acer Netbook.

One Netbook will be given away every day in August.

redcrossblood.org | 1-800-RED CROSS
Determinations (LCDs) and Local Coverage Determinations (NCDs) list specific CPT codes for covered tests, as well as the Medicare-approved ICD-9 codes (diagnosis codes) for those laboratory tests that are reasonable and necessary for the diagnosis or treatment of the ICD-9 codes provided by the ordering clinician. ICD-9 codes supporting medical necessity must be included on the laboratory requisition. The diagnosis must be present for the procedure to be paid and there must be documentation within the patient’s medical record.

Providing our laboratory with accurate and essential diagnostic information is critical to the efficient operation of our laboratory. Without appropriate diagnostic documentation, the laboratory is not reimbursed for the tests performed.

Additionally, diagnostic information can determine whether or not an ABN should be signed. Laboratory Alliance clients may provide either an ICD-9 code or a written diagnosis in the space provided on our requisitions.

Providing diagnostic information when ordering a test not only helps the laboratory operate efficiently and receive payment for its services, it eliminates the time and expense the physician office may incur when responding to requests from the laboratory.

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)

NCD is a national policy statement for a diagnostic laboratory test. It indicates which diagnoses, signs, or symptoms are payable for specific tests.

Local Coverage Determination (LCD)

An LCD is a local policy statement by the local Medicare carrier or fiscal intermediary that indicates which diagnoses, signs or symptoms are payable for specific tests.

Following is a list of tests covered under a NCD:

- Alpha-Fetoprotein
- CA 125
- CA 15-3
- CA 19-9
- CA 27.29
- CBC
- CEA
- Collagen Crosslinks (N-Telopeptide)
- Digoxin
- GGT
- Glycated Hemoglobin
- Hepatitis Panel
- HCG, Quantitative
- HIV, Diagnosis
- HIV, Prognosis
- Serum Iron Studies
- Lipids
- Occult Blood
- PSA (Screen and Diagnostic)
- PT
- PTT
- Thyroid Testing
- Urine Culture

Following is a list of tests covered under the LCDs:

- Acid Phosphatase, Prostatic
- Beta-2-Microglobulin
- BNP
- Calcium, Ionized
- CRP, High Sensitivity
- Erythrocyte Sedimentation Rate (ESR)
- Flow Cytometry
- Hepatic Function Panel
- Hepatitis Tests
- Homocysteine
- Immunocytchemistry
- Magnesium
- PTH
- RAST Tests
- Syphilis Tests
- Vitamin D, 25 OH

When ordering a test that does not meet NCD or LCD guidelines, an Advanced Beneficiary Notice (ABN) should be obtained from the patient. The purpose of the ABN is to give the patient advance notice that Medicare may not pay for the test ordered. When payment is denied as not medically necessary, Laboratory Alliance can only bill the patient if we have received a valid ABN.

You can review the NCD and LCD policies by visiting our website at www.laboratoryalliance.com and selecting Links and Resources.

**Reflex Testing**

Reflex testing is testing that is performed as a result of initial test results. The reflexively ordered test is used to further identify significant diagnostic information required for appropriate patient care.

A list of the reflex tests performed by Laboratory Alliance, when appropriate, is found in our Directory of Services as well as on the back of our test requisitions.

**Panels**

Organ or disease panels will only be billed and reimbursed when all test components are medically necessary. If only some components are medically necessary, or if the physician wishes to order other tests not included in the panel, those tests should be ordered individually.

A list of tests included in the American Medical Association acceptable panels is printed on our requisitions and is found in our Directory of Services.

The Medicare reimbursement for these tests can be found at www.cms.hhs.gov/ClinicalLabFeeSched. Medicaid reimbursement will usually be equal to, or less than, the Medicare reimbursement.

**Clinical Consultation Services**

Appropriate test usage and test ordering may be discussed with Laboratory Alliance’s CEO and Director of Laboratories Michael R. O’Leary, M.D. He may be reached by contacting our Customer Service Department at (315) 461-3008.
Fine needle aspiration (FNA) plays an essential role in the evaluation of the euthyroid patient with a thyroid nodule. It reduces unnecessary surgery for patients with benign nodules and appropriately triages patients with malignant nodules for timely clinical intervention.

It is critical to communicate thyroid FNA interpretations to the referring physician in terms that are succinct, unambiguous and clinically usable. The Bethesda System for Reporting Thyroid Cytopathology (BSRTC) is a new classification which is designed to fulfill these functions.

BSRTC recommends that each thyroid FNA report begin with a general diagnostic category. Each diagnostic category has an implied cancer risk, which ranges from 0-3% for the benign category to virtually 100% for the malignant category. The diagnostic categories are as follows:

I) Nondiagnostic/Unsatisfactory.
II) Benign.
III) Atypia of Undetermined Significance/Follicular Lesion of Undetermined Significance.
IV) Follicular Neoplasm/Suspicious for Follicular Neoplasm.
V) Suspicious for Malignancy.
VI) Malignant.

For several categories (I, III, IV), a consensus on a single name was not reached, so either term is considered acceptable. Also, for some of the categories, some degree of subcategorization is informative and often appropriate.

For example, in the malignant category (category VI), it is critical for patient management to subcategorize the type of malignancy present (papillary thyroid carcinoma, medullary thyroid carcinoma, non-Hodgkin lymphoma, etc).

The most significant change in this new classification system is the addition of a general diagnostic category labeled, “Atypia of Undetermined Significance” (category III). This is generally used for follicular cells (or Hürthle cells) with mild/focal cytologic or architectural atypia, although it can also be used for atypical lymphoid proliferations.

The differential diagnosis for this category is broad, and could include benign lesions (such as adenomatoid nodule, follicular adenoma, Hürthle cell adenoma) as well as malignant lesions (such as follicular carcinoma, Hürthle cell carcinoma, papillary thyroid carcinoma and lymphoma), among other entities.

In general, a repeat FNA after a reasonable interval (at least three months) is the most appropriate follow up for lesions in this category, although in specific clinical settings other management options may be more appropriate.

It is noted that category IV (Follicular Neoplasm/Follicular Lesion or Hürthle Cell Neoplasm/Hürthle Cell Lesion) can also include benign and malignant entities, including adenomatoid nodule, follicular adenoma, Hürthle cell adenoma, follicular carcinoma, and Hürthle cell carcinoma.

The recommended management of lesions in this diagnostic category is generally surgical excision of the lesion, most often lobectomy (with or without frozen section).

There are several optional sections which can be included in the report. The first is the statement of adequacy. Unless the diagnostic category is Nondiagnostic/Unsatisfactory, the specimen is assumed to be adequate for evaluation. However, an explicit statement of adequacy can be included in every report, and is considered optional.

Another option available to the pathologist is the addition of the descriptive findings, usually placed under the diagnostic category. These essentially describe the cytologic findings, and help to explain why the particular diagnostic category was chosen in that specific case.

The last optional section which can be included is a section dealing with notes, comments or recommendations. This can be very useful to the clinician, and could be used to explain why a definite diagnosis could not be reached, or give a differential diagnosis, or give recommendations for follow-up. I believe this is a crucial part of the report, and I almost always give recommendations for follow-up in my reports.

For more information or to discuss The Bethesda System for Thyroid Cytopathology, contact Cytology Department Medical Advisor John Fazio, M.D., at (315) 492-5096 or Cytology Department Technical Manager, Janet Miller, SCT (ASCP) at (315) 410-7211 or by e-mail to janetmiller@lacny.com.

Robin Corlis is Selected by Peers as Corporate CHAMP

Arriving to work with a smile and volunteering for extra assignments is not in her job description, but Senior Medical Technologist Robin Corlis has been doing this since joining the company more than five years ago. In May she was chosen by her co-workers as a Laboratory Alliance CHAMP.

“Robin is a great teacher and a positive role model for her co-workers and often takes new employees under her wing,” says one co-worker. Robin, who works in our Hematology Department, actively participates in career fairs, where she speaks with pride about her medical technology profession.

Robin joined Laboratory Alliance in June 2005 after graduating from Marist College with a degree in medical technology. Experience includes internships in the Chemistry Department at St. Francis Hospital in Poughkeepsie, N.Y., and at the Veteran’s Affairs-Hudson Valley Health Care System in Castle Point, N.Y., where she was trained in microbiology, phlebotomy, urinalysis and hematology. She received Blood Bank training during an internship at Kingston-Benedictine Hospital in Kingston, N.Y.

Consistently demonstrating the qualities of a CHAMP: Caring, Helpfulness, Accuracy, Motivation and Professionalism, we are proud to recognize Robin as our May CHAMP.

Welcoming the CEO of CenterState CEO

Robert Simpson, the new CEO and President of the newly merged Metropolitan Development Association (MDA) and the Syracuse Chamber of Commerce, recently visited Laboratory Alliance for lunch and a tour with CEO and Director of Laboratories Michael R. O’Leary, M.D. and Vice President of Business Development and Marketing Anne Marie Mullin. Dr. O’Leary and Anne Marie explained the history of Laboratory Alliance and our capabilities and services.

The new organization is called CenterState Corporation for Economic Opportunity (CenterState CEO). The non-profit regional growth organization serves individuals, businesses and communities across 12 counties in the heart of New York state, working to achieve economic growth and prosperity through partnerships, planning and problem-solving.

To learn more, visit www.centerstateceo.com.

Anne Marie Mullin Elected to CCH Home Care Board

Anne Marie Mullin, vice president of business development and marketing, was recently elected to the board of CCH Home Care & Palliative Services, Inc. (CCH).

CCH provides home health, including palliative care services, to the residents of Onondaga County, integrating its services with its member organizations as well as other service agencies in the County. CCH is an affiliate of VNA Systems, Inc., which is also comprised of Independent Health Care Services, Inc., the VNA Foundation of Central New York and the Visiting Nurse Association of Central New York, Inc.

CCH is also affiliated with Hospice of Central New York. Anne Marie, elected president of the board of the Hospice Foundation of Central New York in November 2009, has been a member of its board since 2007. She also serves on the Contact Community Service and Mental Health Association board of directors is an active committee member for Francis House, MedTech and other area not-for-profits.
New Employees

Please welcome our new employees

At our Operations Center
Joseph Capogreco – Phlebotomist
L. Dean McCormac – Courier
Brian Palma – Technical Processing Assistant
Mariya Sukhorukov – Medical Technologist
Maria Zych – Phlebotomist

At our Rapid Response Laboratory
at St. Joseph’s Hospital
Deb Gardiner – Medical Technologist
Aslihan Gokce – Medical Technologist

Employee Anniversaries

July, 5 years:
Darrell Bush
Johnathan Daddario
Douglas Trpcevski

August, 5 years:
Abdelkarim Galal
Venett Martin

September, 5 years:
Cristina Lenartowicz
Kathryn Sigona

August, 10 years:
Gary Burns
Audrey Cobb
Therese Conrad
Gabriella Davis
Alan Farmer
Christine Traphagen

Many Take the Corporate Challenge

Laboratory Alliance runners and walkers participated in this year’s JPMorgan Chase Corporate Challenge held on a soggy evening in June. Despite a delay due to weather, the race was completed by more than 7,000 people in all.

Thanks to all who participated and a special appreciation goes out to our Laboratory Alliance Corporate Challenge organizers Becky Reynolds, Nancy Crossett, Kelly Kranz, Lori Anna and Jane Roller.

Runners and walkers (above) take shelter in the tent before the start of the Chase Corporate Challenge, held June 22 at Onondaga Lake Park.

Medical Technologist Kelly Kranz, Operations Center, (right) designed Laboratory Alliance’s T-shirt for the 2010 Chase Corporate Challenge.

Kelly’s T-shirt design was selected by a committee that included representatives from JPMorgan Chase in Syracuse and in New York City as a winner from 259 entries! She was recognized on stage at the event along with Becky Reynolds, our team coordinator.

Photo right, Rachel Elder, M.D., of Pathology Associates of Syracuse and Director of Laboratories at our Rapid Response Laboratory at Crouse Hospital and Information Systems Analyst Matt Vanderwerken wait as the start of the race is postponed more than hour due to heavy rain and thunder.
CALENDAR OF EVENTS

Wednesday, Sept. 8
Auburn Memorial Hospital Foundation Golf Classic, Highland Golf Course, Auburn, N.Y. Laboratory Alliance is a sponsor.

Friday, Sept. 10
St. Joseph’s Hospital Health Center Foundation Annual Golf Classic, Turning Stone Kaluhyat Course. Laboratory Alliance is a sponsor.

Saturday, Sept. 11
Laboratory Alliance Clambake, Spinning Wheel Restaurant, North Syracuse, 5-9 p.m.

Wednesday, Oct. 13
Francis House’s ‘There’s No Place Like Home,’ Horticulture Building, NYS Fairgrounds. Laboratory Alliance is a sponsor.

Friday, Oct. 15
Hospice Foundation of Central New York’s ‘September Song,’ Oncenter, Syracuse. Laboratory Alliance is a sponsor.

Laboratory Alliance is currently running a series of print ads that show how what we do every day impacts thousands of lives. A black and white photograph of a Laboratory Alliance employee at work represents that we are behind the scenes as people live their lives. The people portrayed in the color photos illustrate some of the stages in our lives and why we value good health.

We are dedicated to serve you in sickness and in health.
Laboratory Alliance’s commitment to provide superior service extends to every specimen we receive. It’s why we operate 24/7, 365 days a year. Whether it’s diagnosing disease, assessing the effect of treatment, or confirming one’s good health, we understand the importance of what our testing provides. We perform more than 10 million tests annually...we see the lives they represent.
Our ongoing investment in the latest medical technology and our broad test menu allows us to perform in-house over 90% of the tests sent to us. That means rapid turn-around time of test results for our clients and the patients they serve. What we do every day impacts thousands of lives.

The best course of treatment is dependent on the right diagnosis.
When doctors and patients know more, they can make better choices sooner and plan next steps. These decisions are dependent on reliable laboratory results. Laboratory tests constitute an estimated 70% of the patient’s medical record and are vital to the diagnosis and treatment of illness and disease.
Laboratory Alliance of Central New York performs more than 10 million tests annually. What we do every day impacts thousands of lives.

We may never meet the patients, but we touch them every day.
It’s why we come to work. And it’s why we work so hard to help serve the doctors and patients who depend on us. Laboratory Alliance is the largest, most comprehensive clinical and anatomic pathology laboratory in Central New York. Our rapid delivery of test results, expertise of staff and state-of-the-art equipment and technology allow us to help our clients make better informed decisions. We often only know these patients through barcodes, results and statistics, but these numbers represent our fathers and sons, mothers and daughters, friends and neighbors. What we do every day impacts thousands of lives.

Mark Your Calendar for this Musical Treat

Beyond Motown: An Explosion of Rhythm and Blues
Starring American Idol Finalist Melinda Doolittle
October 15, 2010 at the Oncenter

Enjoy an evening of great music and support Hospice of Central New York on Friday, Oct. 15. American Idol Finalist Melinda Doolittle will headline and local favorite Ronnie Leigh will share his outstanding vocal talents with Artistic Director Fred Willard and the Central New York Jazz Orchestra. Tickets and sponsorships are available — call (315) 634-1100 or visit www.hospicecny.org.

LAblines is a quarterly publication by LABORATORY ALLIANCE of CNY.
Comments, suggestions or inquiries should be directed to Anne Marie Mullin, Vice President of Business Development and Marketing, (315) 461-3036, or by e-mail to annemariemullin@lacny.com.