



Celebrating 10 years

LABlines

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Laboratory Medicine: A National Status Report

By Michael R. O'Leary, M.D., CEO

The history of laboratory medicine is replete with significant milestones and extends back to

the first recorded examination of human bodily fluids by the ancient Greek physician Hippocrates around 300 BC. Two thousand years later, the first clinical laboratory opened in 1896 at the Johns Hopkins Hospital.

The discovery of the disease-causing epidemics such as tuberculosis, diphthe-

ria and cholera and the development of tests to detect their presence throughout the end of the 19th century propelled the laboratory to a position of importance by the early 20th century. Beginning in 1926, all hospitals accredited by the

“...medical laboratories in the United States perform over 7 billion tests, influencing an estimated 70% of medical decisions... and testing accounts for only 2.3% of annual U.S. healthcare costs!”

American College of Surgeons were required to establish a laboratory under the direction of a physician.

Today, the clinical laboratory serves a vital role in the healthcare system which encompasses research, clinical care and public health surveil-

lance. Each year, the 200,000 plus CLIA-certified medical laboratories in the United States perform over 7 billion tests, influencing an estimated 70% of medical decisions. Yet despite this significant impact on clinical decision-making and health outcomes, laboratory testing accounts for only 2.3% of annual U.S. healthcare costs!

With ever growing pressures on labs to do more with less, a comprehensive analysis of key factors affecting lab medicine however, was missing. Now, a two-year effort by the Centers for Disease Control (CDC) Division of Laboratory Systems has given stakeholders, including policy makers, a snapshot of where the field stands today. “Laboratory Medicine: A National Status Report” was published in May and describes the challenges and prospects that affect clinical laboratories in the U.S.

The purpose of the report, according to the CDC, is to lay the groundwork for transforming laboratory medicine over the next decade. The 384-page report was written by the Lewin Group, a health and human services consulting firm based in Falls Church, Virginia.

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Laboratory Alliance Receives Gold Seal of Approval

By demonstrating compliance with The Joint Commission's national standards for health care quality and safety, Laboratory Alliance has once again earned The Joint Commission's Gold Seal of Approval™.

“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 Vickie Company, Director of Quality Assurance. Earlier this year, The Joint

Commission reevaluated the laboratory's performance in complying with nearly 300 standards related to quality control, safety, infection control, leader-

ship, management of human resources, management of information, ongoing performance improvement activities and other issues.

Founded in 1951, The Joint Commission is dedicated to improving the safety and quality of the nation's health care through voluntary accreditation.

“The accreditation process helps promote continuous, systematic and organization-wide improvement in health care organizations,” says Margaret Peck, executive director, Laboratory Accreditation Program, The Joint Commission. “Achieving accreditation demonstrates Laboratory Alliance's commitment to providing high quality and safe services.”

Company said efforts to improve don't stop when The Joint Commission survey is over. “Meeting the standards and achieving excellence is a continuous process,” she said. “No matter how well we did today, we continue to strive to do better tomorrow.”



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Laboratory Medicine: A National Status Report

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This report compiled and analyzed data from published and unpublished literature, government databases, market research reports and input from laboratory experts and significant government officials. While most lab leaders praise the report as an accurate overview of significant factors that affect laboratory medicine today, how the document will drive improvements is still uncertain. Clearly, the report is a welcomed affirmation of the struggle that lab professionals have faced for recognition of their contributions and the value it adds to the U.S. healthcare system. Many in the laboratory industry believe that the report substantiates what laboratories have been saying for decades about the need to improve reimbursement as well as government oversight of laboratory practices. However, we must remember that it is really a first step that needs to be followed up with specific recommendations to address the problems identified. Organizations that represent laboratory medicine and pathology hope that the policy makers will use the data to make much needed changes in reimbursement and regulation of lab tests. The relevance of the report is that now there is a government-commissioned document that supports what many in the field have been saying.

A Comprehensive Scope

Concern that policymakers' lack of a firm understanding of the field of labora-

tory medicine was one of the factors that prompted the CDC to initiate this national effort to identify and evaluate best practices in lab medicine.

"We have felt for some time that there needed to be a document that substantiates the scope of laboratory medicine in the United States," explained Dr. Joe Boone, Acting Director of the CDC Division of Laboratory Systems and the administrator of the project. "Its primary focus is to help those who are not laboratory professionals — policy makers, politicians, and others — to better understand the field as well as the nature of constraints that influence or affect laboratory operations and practices."

The report examines in detail the key factors affecting the laboratory medicine sector, and is organized into chapters on the following main topics:

- Value of Laboratory Medicine
- Market Profile of the Laboratory Medicine Sector
- Laboratory Medicine Workforce
- Quality in the Total Testing Process
- Quality Systems and Performance Measurement
- Laboratory Information Systems
- Federal Regulatory Oversight of Laboratory Medicine
- Reimbursement for Laboratory Medicine

With regard to the value of laboratory medicine, it is well known that testing has a major impact on clinical decisions, providing physicians, nurses and other healthcare providers with information that aids in the prevention, diagnosis, treatment and management of disease. Despite this extensive scope of influence, spending on laboratory services account for only 2.3 % of healthcare expenditures and 2% of Medicare expenditures.

Reimbursement Change is Needed

Low reimbursement rates have plagued labs for a number of years. In 2000, the Institute of Medicine (IOM) issued a report titled "Medicare Laboratory Payment Policy: Now and in the Future." It then stated that existing mechanisms for keeping payments up to date are inadequate. Today, eight years later, the same issues still affect labs. The Medicare program exerts the strongest influence on U.S. laboratory services

payment. All public payers and approximately 67% of private payers use Medicare's payment methodologies as the basis for their own and as tools for negotiating discounts with providers. Redesign of the current Medicare payment system is needed to meet the growing scientific, technical, clinical and economic challenges of the U.S. healthcare system.

The report also correctly concludes that continued use of **56 different fee schedules** nationwide is inefficient and unnecessarily complex. For certain commonly ordered tests, the multiple fee schedules result in large regional variations, but for other tests, national fee limitations result in inadequate Medicare payments. Additionally, Medicare statutes restrict payment for screening and other preventative technologies and services, unless approved by Congress. Adding Medicare coverage for such services on a case by case basis via legislation is cumbersome and impedes access to certain proven and beneficial tests.

A Call to Action

As we approach the close of the first decade of the 21st century, we must address the fact that healthcare now accounts for **one-sixth** of the U.S. economy! Laboratory medicine guides, and is often the pivotal determinant in, decisions that influence the magnitude and allocation of resources in this burgeoning sector.

Any efforts to improve the quality of healthcare, let alone transform it, must engage laboratory medicine and its work force, provide systems for ensuring quality, and systems for managing information. Such efforts must also confront the complex and often inadequate regulatory and payment systems that adversely affect laboratories across the country. Further, it will be incumbent upon those in laboratory medicine to demonstrate its value continually, along with the dimensions of access, informed decisions, patient and provider satisfaction, healthcare outcomes and cost effectiveness. The entire "Laboratory Medicine: A National Status Report" document may be downloaded at www.futurelabmedicine.org.

A Key Player in the Health of Central New York



Microbiology/Virology



These three articles were written by
Paul A. Granato, Ph.D., Director of Microbiology

Update on the QuantiFERON-TB Gold Test

Our Microbiology Department now offers an upgraded and improved version of the QuantiFERON-TB Gold Test. The new assay is called the QuantiFERON-TB Gold In-Tube Test which offers increased test sensitivity because it tests for the presence of three, rather than the previous two, mycobacterial protein antigens.

The immune response to infection with *M. tuberculosis* is predominantly a Cell Mediated Immune (CMI) response 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 tuber-

culosis 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 non-tuberculous 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 TB infected individuals respond to all three antigens, many infected individuals may respond to only one. Unlike skin testing, there

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Clostridium difficile Disease and Expanded Test Services

Clostridium difficile infection is responsible for approximately 3 million cases of diarrhea and colitis annually in the United States. The mortality rate is 1 to 2.5 percent. Early diagnosis and prompt aggressive treatment are critical in managing *C. difficile*-associated diarrhea.

Major predisposing factors for symptomatic *C. difficile* colitis include antibiotic therapy; advanced age; multiple, severe underlying diseases; and a faulty immune response to *C. difficile* toxins.

The virulence of *C. difficile* is associated with the organism's ability to produce an enterotoxin and/or a cytotoxin, called toxin A and toxin B respectively. Recently, another *C. difficile* toxin, called binary toxin, has been characterized whose function and involvement in disease is currently unknown.

The laboratory diagnosis of *C. difficile* infection is based upon the detection of toxin A and/or B in fecal samples. The most popular laboratory tests are a cytotoxin assay which is slow and labor-

intensive or an EIA method which is much easier to perform.

Each method has its own advantages and limitations but most laboratories use the EIA method because of convenience and short turnaround times.

Laboratory Alliance's Microbiology Department performs an EIA test that screens for toxin A and toxin B in stool samples. Previously, this manual test was performed only once each day. Laboratory Alliance has recently acquired an automated instrument platform that will allow the test to be performed twice each week day and once on holidays and each day of the weekend.

This expanded test service will result in shorter turnaround times that will have considerable impact in controlling the transmission of this disease among hospitalized and nursing home patients. Importantly, physicians are reminded that experts recommend sending as many as three stool samples to rule out disease, if initial tests are negative.

A Report on Mumps In Onondaga County

The Onondaga County Department of Health (OCDH) has reported at least four confirmed and several probable cases of mumps in Onondaga County. All infected individuals had a documented history of vaccination with at least one dose of MMR. A number of other cases are being investigated at the time of preparation of this article (Sept. 12).

It is imperative that physicians and other health care providers notify the OCDH at (315) 435-3236 if a patient is suspected of having mumps. The following represents some useful and important information regarding mumps provided by the Centers for Disease Control and Prevention and the NYSDOH.

Background

Mumps is an acute viral illness associated with fever, headache, muscle aches, tiredness, and loss of appetite and is marked by swelling of any or all salivary glands (usually parotid, but may involve submandibular or sublingual). Although usually a self-limited illness, complications of mumps may include orchitis, oophoritis, encephalitis/meningitis, mastitis, spontaneous abortion and deafness. Mumps occurs sporadically year-round throughout the world; rarely, outbreaks have occurred among populations with variable levels of vaccination.

Transmission

Mumps is transmitted through respiratory droplets or through direct contact with saliva or respiratory secretions. It is generally believed that casual contact is insufficient for transmission. The incubation period is 12-25 days.

Case Definition

A case of mumps is defined as a person who has > 2 days of parotid and/or other salivary gland swelling without other apparent cause.

Differential Diagnosis

Other viral etiologies such as parainfluenza virus, Epstein-Barr virus, cytomegalovirus, enterovirus, lymphocytic choriomeningitis virus (LCMV), and HIV are possible causes of parotid swelling, but much less frequently than mumps. History and physical exam are crucial in directing suspicion toward or away from mumps.

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Herpes Simplex Virus: Making Sense of Serology

By Jayne L. Healey, M.D., Assistant Director of Laboratories

Herpes simplex virus (HSV) is a common human pathogen, with more than 90% of the world's adult population demonstrating anti-HSV antibodies.

HSV is characterized into two distinct serotypes, HSV-1 and HSV-2. HSV-1 is typically associated with ulcerative lesions of the mouth and eyes. HSV-2 primarily associated with genital and neonatal infections; however, there has been a recent upsurge in HSV-1 primary genital infection. Vertical transmission of HSV can result in devastating disseminated infection in the neonate, with a mortality rate exceeding 70%. The majority of infants with congenital HSV are born to asymptomatic mothers, prompting some to advocate for HSV screening in all pregnant women. Rates of vertical transmission are much higher in primary genital infection than in recurrent infection.

Although viral culture remains the gold standard for diagnosis, it is slow and relatively insensitive. Serological testing is a rapid and sensitive adjunct to viral isolation. It may be used in confirming clinical diagnoses in patients with recurrent lesions, atypical lesions or with healing lesions and negative HSV cultures. It is also useful for demonstrating recent seroconversion, documenting symptomatic past infections and identifying at-risk immunocompromised patients. Perhaps most importantly, serological testing aids in the identification of asymptomatic carriers. In primary HSV infections, IgM antibodies become detectable approximately one week after onset of symptoms and are undetectable after two months. Detection of anti-HSV IgG is possible approximately two weeks after the onset of infection, and IgG antibodies persist at various levels for life.

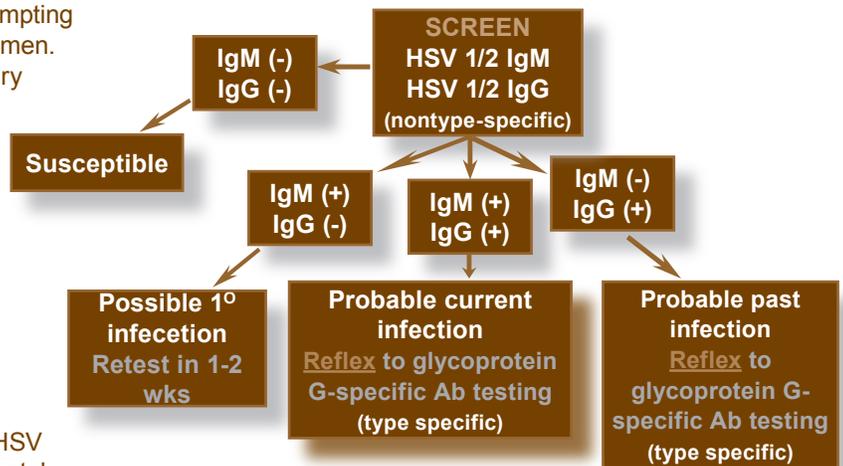
Distinction between HSV-1 and HSV-2 infection is often clinically significant. HSV-1 is the principal serotype in most herpes encephalitis cases, whereas HSV-2 shows more association with herpes meningitis. Genital HSV-2 infections tend to recur much more frequently than HSV-1 genital infections. The two serotypes also differ in their susceptibility to antiviral therapy. Studies indicate that probably all HSV-2 seropositive people intermittently shed virus. Unfortunately, only 10-25% of people with HSV-2 antibodies are aware that they have genital antiviral herpes.

Type-specific IgG testing is now available using highly sensitive and specific ELISA methodology. This testing is directed against the unique glycoprotein G of HSV-1 and HSV-2. Screening for HSV using anti-glycoprotein G IgG antibodies is not recommended, as a significant percentage of people (5-10%) do not produce antibodies against glycoprotein G. A small percentage of glycoprotein G-deficient HSV isolates have also been reported.

HSV serological testing is performed at Laboratory Alliance on Monday, Wednesday, and Friday. Qualitative HSV screening is accomplished by using the Diamedix

Immunosimplicity® Is-HSV 1&2 IgG and Is-HSV-1&2 IgM enzyme immunoassays. Specimens determined to be positive for HSV 1&2 IgG screening are reflexively typed using the HerpeSelect® 1 ELISA IgG and HerpeSelect® 2 ELISA IgG assays. The results of both the Diamedix® and HerpeSelect® assays are reported as antibody indices and cannot be correlated to end-point titers. The magnitude of the measured result, above the cutoff, is not indicative of the total amount of antibody present and should not be interpreted quantitatively.

The following diagram depicts the algorithm utilized by Laboratory Alliance for HSV serological testing:



HSV serological testing should not be used as the sole criterion for the diagnosis of active herpes simplex infection in pregnant women. The presence of HSV should be demonstrated by isolation of live virus. The table below may be useful for the virological and serological interpretation of genital lesions:

	HSV -2 by culture, DFA or PCR	HSV -1 IgG	HSV -2 IgG	Interpretation
"New" lesions	+	+/-	-	Acute HSV -2 infection likely
	+	+/-	-	Recurrent HSV -2 infection likely
No lesions	N/A	-	-	Susceptible to HSV -1 and HSV -2 infection
	N/A	+	-	Susceptible to HSV -2 infection
Recurrent lesions	+	+/-	+	Recurrent HSV -2 infection
	-	-	+	Possible HSV -2 infection; consider other causes of genital lesions

For questions or concerns regarding this test service, please contact Cheryl Haskins, Chemistry Manager, at (315) 410-7014.

Hemoglobin A1C: Teaching an Old Test New Tricks?

By Jayne L. Healey, M.D., Assistant Director of Laboratories

The hemoglobin A1C assay (HbA1C) is widely accepted as a reliable means for assessing chronic glycemia (low blood glucose). Its close association with risk for long-term complications has led the American Diabetes Association (ADA) to establish specific A1C targets for diabetes care. A1C testing measures the percentage of glycated hemoglobin in the blood and represents the average blood glucose during the preceding 120 days.

The ADA recommends that HbA1C be measured at least twice annually in diabetics meeting treatment goals and with stable glycemic control. In patients not meeting treatment goals or with recent changes in therapy, A1C testing should be performed quarterly.

Although HbA1C measurement is a reliable and standardized assay, results are reported in terms unfamiliar to patients (% glycated hemoglobin). Results of daily fingerstick glucose checks by diabetics are expressed as milligrams per deciliter (mg/dl). A recent major study examined the relationship between daily glucose monitoring and HbA1C levels, arriving at a method for translating A1C into an average glucose value – estimated average glucose (eAG).

The table below is a quick reference chart for conversion of A1C to eAG:

A1C %	eAG mg/dl
5	97
5.5	111
6	126
6.5	140
7	154
7.5	169
8	183
8.5	197
9	212
9.5	226
10	240
10.5	254
11	269
11.5	283
12	298

$eAG \text{ (mg/dl)} = 28.7 \times A1C - 46.7$

The eAG uses the same values and units as home glucometers and fasting blood glucose levels on lab reports. Clinicians may consider providing eAG to patients to help them better understand the relationship between daily glucose monitoring and long-term control. Patients with meters that display an “average” glucose may note that the calculated eAG is consistently higher for the same time period. This is because most fingersticks are performed when blood glucose levels are low (before meals) rather than when they are high. The eAG represents 24/7 glucose levels over the same time period and is likely to be higher.

As with any assay, there are a number of factors that may interfere with accurate A1C measurement. Any condition that shortens red blood cell survival falsely lowers HbA1C test results, regardless of the test method used. This may be seen in such conditions as sickle cell anemia, hemoglobin C disease, thalassemia, etc. Alternative forms of testing, such as glycated albumin, should be considered for these patients.

Iron deficiency, hypertriglyceridemia, hyperbilirubinemia, uremia (carbamyated Hb), chronic alcoholism, chronic aspirin ingestion (acetylated Hb) and opiate addiction may all interfere with some assay methods, falsely increasing results. High doses of vitamins C or E may inhibit glycation of hemoglobin, thus lowering the A1C level and rendering it an unreliable means of assessing glycemic control.

The presence of certain hemoglobin variants (e.g. hemoglobin E trait) can affect the accuracy of A1C measurements, depending upon the variant and the specific A1C method. If a discrepancy is noted between results of home glucose monitoring and A1C values, consideration should be given to screening for a hemoglobinopathy.

For questions or more information on hemoglobin A1C testing, please contact Cheryl Haskins, Chemistry Manager, at (315) 410-7014.

We Welcome New Clients

Liverpool Dialysis Center
STAT testing services
Syracuse, N.Y.

Fletcher Allen Healthcare
Limited testing
Burlington, Vt.

Madison County Health Department
Limited testing
Wampsville, N.Y.

Nantucket Cottage Hospital
Limited testing
Nantucket, Mass.



Doing our Part for a Greener Tomorrow

Laboratory Alliance is doing its part to become a greener workplace. As a first step, a “Green Committee” has been formed at our Operations Center located in Electronics Business Park in Liverpool.

Employees at several of our locations have been enjoying the benefits of carpooling.

Stay tuned for more information that will be disseminated in the coming months by the “Green Team.”



Congratulations to Claire, Our New CHAMP!

By Barbara Guifrida, Vice President of Human Resources

Laboratory Alliance presented its CHAMP award to **Claire Huchzermeier** at the company clambake on Sept. 13. Claire has worked as a Medical Technologist at the Rapid Response Laboratory at St. Joseph's Hospital since the company was founded on Jan. 1, 1998.

Prior to that, Claire was employed as a medical technologist in the laboratory at St. Joseph's Hospital Health Center since April 11, 1994.

The professional recognition took into consideration nominations submitted to the Employee Recognition Committee. Co-workers describe Claire as "...fair, consistent and professional at all times," "... a pleasure to work with and will happily lend a helping hand whenever needed."

The Committee thanks everyone who participated in the recognition program and is now accepting nominations for the next CHAMP recognition. The deadline for nominations is Dec. 1.



Medical Technologist Claire Huchzermeier, (right) accepts the CHAMP award from Barb Guifrida, Vice President of Human Resources (center). Chris Garritano (left) is chair of the Employee Recognition Committee.



People in the News



Gina Potenza, Director of Information Systems, was recently appointed as a member of a subcommittee of the Clinical and Laboratory Standards Institute (CLSI). She will serve on the Subcommittee

on Planning for Challenges to Clinical Laboratory Operations During a Disaster.

The CLSI is a global, nonprofit, standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community.

Gina, a Certified Business Continuity Planner, leads the Business Continuity Program for Laboratory Alliance in her role as director of information systems.

Our featured department is the Central Receiving Department at our Rapid Response Laboratory at Crouse Hospital.

They include, left to right, John Denhaese, Pat Lipchak, Adam Nappa, Jill Rudnick, Erika Nicholson, Carol Smith and Alex Berlucchi.

Erika recently relocated to the Microbiology Department at our Operations Center and Adam now works in our Pathology Department.

Missing from the photo are Sally Bien, Gabriella Davis, Cara Johnson, Michele Scott, Eileen Sheehan, Lynn Stevens and Peg Thompson.



Featured Department



LA Newsmakers

New Employees

Please welcome our new employees:

At our Operations Center

Rachael Fullem, R & D Specialist

Kimberly Johnson, Phlebotomist

Matthew Kearney Jr., Technical Administrative Assistant

Denise McDonald, Phlebotomist

Brenda Milliman, Phlebotomist

Roy Philpot, Laboratory Office Assistant

Nicole Scalzo, Laboratory Office Assistant

Elizette Yale, Laboratory Office Assistant

At our Rapid Response Laboratory at Community General Hospital

Colleen Poirier, Medical Technologist

At our Rapid Response Laboratory at Crouse Hospital

Lynn Stevens, Technical Processing Assistant

Holly Zehr, Medical Technologist

At our Rapid Response Laboratory at St. Joseph's Hospital Health Center

Kim Ostrander, Laboratory Office Assistant

Alescia Porceng, Technical Processing Assistant



Laboratory Alliance recently participated as an exhibitor in the 2008 Upstate American College of Obstetricians and Gynecologists (ACOG) District II/NY Annual Upstate Meeting held July 18-19 at the Turning Stone Resort in Verona, N.Y.

The winner of the raffle was Ann Marie Barry, Billing Director at Associates for Women's Medicine, pictured on the right along with Ann Marie Derecola, Program Director for Laboratory Alliance.

Congratulations

To **Shelli Bregman DO**, a pathologist with Pathology Associates of Syracuse at Crouse Hospital, on her marriage to Bob Gallamore on Aug. 2.

To **Sara Clarke**, Operations Center, on her marriage to Bryan Fellows.

To **Adam Nappa**, Crouse RRL, on his marriage to Halina Wilke.

To **Carrie Nappa**, Operations Center, and her husband Matt, on the birth of their baby boy Cayden Matthew, born July 23.

Employee Anniversaries

September

5 Years

Kathleen Campanaro

Gursimran Dhillon

Angela Panzino

10 Years

Joe Bertolero

Joan Bonaparte

Michelle Botwinick

Dru Ellen Clay

Josephine Gervasi

Dede Haefele

Linda Hernandez

Daria Lebduska

Marilyn LeClair

Sue Maloney

Deb Neverette

Sister Maria Grace

Sharon Reif

Jeanette Reynolds

Heidi Jo Robinson

Antoinette Tortora

Alan Tucker

Olga Volyanik

Mary Warter

Elsie Wilson

October

5 Years

John Denhaese

Catherine Reid

Eileen Sheehan

10 Years

Kelly Brunelle

Judy Burns

Christine Carrington

Anne Chamberlain

Michele Connor

Jackie Fisher

Shelley Murphy

Kathy Real

Jane Roller

Ellen Searles

John Vormwald

Katrina Zeglin



Water Balloon Toss drew a crowd at the company clambake, held Sept. 13 at The Spinning Wheel restaurant in North Syracuse.

Updated QuantiFERON-TB Gold Test

Continued from page 6

is no stratification of the diagnostic-cut-off based on patient history, BCG vaccination status or risk factors, and thus the answer 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.

The QuantiFERON-TB Gold In-Tube test has been evaluated for use with immunocompetent healthy adults with and without identifiable risk factors for latent TB infection (LTBI). QuantiFERON-TB Gold has also been evaluated in individuals with culture-proven TB disease.

It is important to note that the Quanti-FERON-TB Gold In-Tube Test can be used for people who are being tested for TB infection, with the following limitations. The test has not been evaluated for use in children (<17 years), infants, pregnant women, immunocompromised individuals (including HIV positive individuals), or people with certain clinical conditions predisposing immunosuppression (i.e. diabetes, silicosis, cancers, organ transplants), or those taking immunosuppressive medication.

Clinicians should use clinical judgment in interpretation of test results, particularly when excluding TB infection as a diagnosis.

A Report on Mumps in Onondaga County

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Confirmatory Diagnosis

Clinical suspicion must be confirmed with laboratory tests. Every suspected case should have blood drawn for mumps IgM and IgG at the time of clinical diagnosis even if the patient has a history of vaccination. If acute IgM is negative, a convalescent sample for IgM and IgG (drawn 14-21 days later) is necessary for confirmation.

If duration of parotitis is < 5 days, an attempt to isolate the virus should be made. Viral swabs should be collected by rubbing the interior cheek (buccal mucosa) at the Stensen duct (where the parotid gland empties into the mouth) after massage of the parotid gland for 30 seconds.

Interpretation

Clinical history and exam must be considered with test results to confirm a diagnosis of mumps.

IgM: A positive result in a clinically-consistent case confirms the diagnosis. A negative IgM result means mumps may not be the cause, but DOES NOT rule out mumps, especially in the immunized. A positive result in an asymptomatic patient is inconclusive.

IgG: A positive IgG result in an acute sample does not rule out mumps. Acute and convalescent samples must be run at the same time. A conversion from negative to positive or a > 4-fold rise of IgG between acute and convalescent sera confirms the diagnosis.

Swab: Positive culture confirms mumps. Negative is inconclusive. Viral culture must specifically request "culture for mumps virus."

Calendar of Events

Wednesday, Oct. 15

"There's No Place Like Home" fundraiser to benefit Francis House, Horticulture Building, NYS Fairgrounds. *Laboratory Alliance is a corporate sponsor.*

Thursday, Oct. 16

Greater Syracuse Chamber of Commerce Economic Champions in Central New York, Holiday Inn, Electronics Parkway, Liverpool. *Laboratory Alliance will be recognized.*

Friday, Oct. 24

"Jeans and Jewels Gala" to benefit Community General Hospital Foundation, Hotel Syracuse. *Laboratory Alliance is a corporate sponsor.*

Saturday, Oct. 25

Sweet Sensations fundraiser to benefit the Franciscan Northside Ministries, at their facility at 804 N. Salina St. *Laboratory Alliance is a corporate sponsor.*

Wednesday, Oct. 29-Thursday, Oct. 30

Clinical Laboratory Management Association (CLMA) and American Association for Clinical Chemistry (AACC) Annual Conference and Exhibition, Turning Stone Resort and Casino, Verona, N.Y. *Laboratory Alliance is a corporate sponsor and exhibitor.*

Testing for parainfluenza, EBV, and/or CMV can be performed to rule out alternative causes of parotitis.

Isolation and Infection Control

Symptomatic mumps cases must be isolated for 5 days after onset of parotitis. Susceptible close contacts should be vaccinated for mumps (recommended as MMR). In a sensitive setting such as a school, day care, or health care facility, susceptible individuals should be excluded for 26 days after last potential exposure (e.g., onset of parotitis in final case). Susceptible individuals may return once they are vaccinated.



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Comments, suggestions or inquiries
should be directed to

Anne Marie Mullin, Vice President,
Business Development and Marketing
at (315) 461-3036,

or by e-mail to annemariemullin@lacny.com.