Laboratory Alliance is on a continuous journey of quality improvement. Workflow processes are evaluated daily as we look for opportunities to improve efficiency and, more importantly, accuracy. “Doing what is in the best interest of the patient” is the motto that defines our work, so positive identification is always our number one focus.

In 2010, the College of American Pathologists (CAP) conducted a study focusing on mislabeling of surgical pathology specimens, blocks and slides. The study looked at hundreds of thousands of cases at 136 institutions to determine where errors occur in the procurement, accessioning and processing of surgical specimens. Alarmingly, the study reviewed greater than 427,000 cases and found mislabeled rates of 1.1 per thousand cases, 1.0 per thousand specimens, 1.7 per thousand blocks, and 1.1 per thousand slides. In addition, all New York state laboratories holding a New York State Department of Health (DOH) permit received a letter from the DOH to evaluate all procedures in place to ensure that risk of patient misidentification is mitigated. This action was based on a well-documented instance of patient mis-identification that occurred at a laboratory downstate.

Realizing the devastating impact of one wrong diagnosis of a patient due to a mislabeled specimen, cassette, block or slide, Laboratory Alliance began searching for a software solution that would eliminate the human element from the process. Barcode solutions have proven to be very effective in reducing labeling errors in the clinical laboratory. Therefore, we should be handling tissue specimens in the same way. Until recently, available solutions in anatomic pathology were minimal, or had not reached a point in their development to be an effective software and hardware solution.

Surgical pathology is a very labor-intensive process that involves many steps. Tissue samples are placed into processing cassettes at the gross disection step and, after processing in paraffin wax, the tissue is embedded in additional wax to produce a tissue block. For many years histotechnicians embedded surgical samples, cut paper-thin sections of tissue with a microtome and attached it to a slide labeled with a handwritten block number. After staining the slide, another individual applied a printed label containing the block number and the patient name over the handwritten information. Up until a few years ago this was the only process available.

We all know the age-old saying “to err is human.” The possibility of transcribing information incorrectly or having difficulty reading someone’s handwriting was always looming in the background. That is why the staff in our Histology Department welcomed Ventana’s Vantage specimen identification and tracking system.

Patient safety and sample integrity is a major focus of Laboratory Alliance and regulatory agencies. Cassette barcode labelers along with Ventana’s Vantage Workflow Solution identification and tracking system offered a way to both identify and track anatomic pathology specimens through the entire process of accessioning, grossing, processing, embedding, microtomy and transport of the slide back to the pathologist’s desk for review and diagnosis. This type of technology eliminated a major source of human error.

Prior to obtaining cassette labelers that could print a 2D barcode, a technician had to handwrite a tracking number from the specimen block onto the slide. The handwritten information was then matched to a paper label containing the block number and patient name. Given our volume of 160,000 blocks per year — 600 to 800 per day — and 250,000 slides per year — 984 slides per day — our manual process was susceptible to error. The cassette labelers, which are interfaced to our Laboratory Information System, print a 2D barcode onto each cassette. The Vantage system reads the 2D barcode to positively identify the specimen through the whole process.

With this system,

• the pathologist or pathologists’ assistant at the grossing station verifies that he or she is matching the right specimen with the right cassette; then,
New Testosterone Test Available for Females, Children

By Cheryl M. Hawkins, MS, MT(ASCP)SC, Manager, Chemistry and Referral Testing

Laboratory Alliance now offers a highly sophisticated in-house automated system to evaluate testosterone levels in females and children. The test may also be useful for monitoring male patients diagnosed with hypogonadism.

Although testosterone is most notable for its androgenic properties, and its importance for male health, it is also important for female health. The primary function of testosterone in the male is as a sex hormone; it is responsible for the development of male sex organs and secondary sexual characteristics such as increased muscle, bone mass and the growth of body hair. The primary role of testosterone in females is as an estrogen precursor. In both males and females, testosterone is important for health and plays an important role in bone metabolism, bone remodeling and prevention of osteoporosis.

Our new assay uses liquid chromatography with tandem mass spectrometry detection, and is based on our in-house test menu at Testosterone by LC/MS/MS. Females or Children. With a low end reporting limit of 2.5 ng/dL, the new test can measure low concentrations of testosterone typically found in women and children, hypogonadal men or patients undergoing antiandrogenic therapies. The circulating concentration of testosterone in women is only five to ten percent of that in men. In children, the circulating concentration of testosterone is age and sex dependent with reference ranges extending down to less than five percent of the adult male testosterone.

Because of its increased sensitivity, LC/MS/MS is the preferred testing method for these patients. Although automated immunoassays are widely used for measuring testosterone, most lack the precision at low levels that is required for supporting reliable clinical decisions,” said Cheryl Hawkins, manager of Chemistry and Referral Testing. “Our new assay has the sensitivity and specificity necessary to accurately and precisely measure these low levels in hypogonadal populations. To help our clients select the most appropriate assay for their patients, we have designated this assay as being for females and children under age 14, but there are some males that may also need this more sensitive testing. Examples are teens with delayed puberty or hypogonadal adult men.”

Testosterone in serum is largely protein-bound to sex hormone binding globulin (SHBG) and only loosely bound to albumin. A small fraction of testosterone in serum remains as the free hormone. It is the free and weakly bound fractions that are biologically active. “While working on this project, we also decided to bring in a new automated immunoassay for SHBG. Now that we have this assay in place, we are able to report free testosterone and bioavailable testosterone using highs sensitivity,” said Ms. Hawkins. “Similar calculations are used with the LC/MS/MS assay and with the immunoassay allowing us to report estimates of the biologically active fractions for male, female and pediatric patient populations.”

The table below outlines our full complement of testosterone testing capabilities:

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Code</th>
<th>Includes</th>
<th>Suggested patient population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone</td>
<td>TSTR</td>
<td>Total testosterone by immunoassay</td>
<td>Adult males, including boys 14 and older</td>
</tr>
<tr>
<td>Testosterone LC</td>
<td>TSTLC</td>
<td>Total testosterone by LCMS/MS</td>
<td>Females, children, hypogonadal males</td>
</tr>
<tr>
<td>Testosterone, Free and Total</td>
<td>TSTRF</td>
<td>Total testosterone by immunoassay, SHBG, calculated bioavailable testosterone and % free testosterone</td>
<td>Adult males, including boys 14 years and older</td>
</tr>
<tr>
<td>Testosterone, LC and Total</td>
<td>TSTLCF</td>
<td>Total testosterone by LC/MS/MS, SHBG and calculated free testosterone</td>
<td>Females, children, hypogonadal males</td>
</tr>
<tr>
<td>Testosterone, Bioavailable</td>
<td>TSTRB</td>
<td>Total testosterone by immunoassay, SHBG, calculated bioavailable testosterone and % free testosterone</td>
<td>Adult males, including boys 14 years and older</td>
</tr>
<tr>
<td>Testosterone LC, Bioavailable</td>
<td>TSTLCB</td>
<td>Total testosterone by LC/MS/MS, SHBG, calculated bioavailable testosterone and free testosterone</td>
<td>Females, children, hypogonadal males</td>
</tr>
</tbody>
</table>

Men Should Check Testosterone Levels Before Starting Replacement Therapy

Recent headlines read that testosterone prescriptions have tripled over the past decade and the “low T campaign” has spurred some medical professionals, and the media, to ask “what about the women?”

The Endocrine Society, the medical group that sets clinical guidelines for testosterone replacement therapy, has recommended that testosterone be used only in men who have unequivocally low testosterone levels. A study in the *Journal of Medicine* recently noted that many men who obtain testosterone prescriptions do not have evidence of deficiency. Researchers are concerned that ads for testosterone prescriptions “may be driving a potentially worrisome amount of overtreatment,” ABC World News reported in June, saying between 2001 and 2011, testosterone prescriptions tripled among men over 40, while 25% were put on testosterone without having their levels checked first. The *New England Journal of Medicine* reported “only about 2% of men over 40 should be getting any boost at all,” because while it can increase muscle mass and boost sex drive, some doctors believe too much testosterone may raise the risk of prostate cancer and liver damage.

Laboratory Alliance recommends that anyone considering testosterone supplements talk to a doctor to request that his levels are tested. This involves a simple blood collection. Many patients already have blood tests for PSA or cholesterol screening as part of their routine health care; the specimen for the testosterone levels can conveniently be collected at the same time. For more information, contact our Customer Service Department at 315-461-3008.
Sentinel Antibiotic Susceptibility Prevalence Studies For Groups A and B Streptococci

By Russell Rawling, MS, M(ASCP)/SM, RN(M)/MSM, Microbiology Manager

Sentinel antibiotic susceptibility prevalence studies for groups A and B streptococci are performed at least biannually by our Microbiology Department to monitor the emergence of resistance to select antimicrobial agents, namely penicillin, erythromycin and clindamycin.

Group A and group B streptococcal isolates were collected from patient specimens from various physician practices and/or area hospitals throughout Onondaga County so that the results would not be biased by geographic location or physician practice specialty. The following highlights the results of these studies.

Group A streptococcal study results
From June 4 to July 26, 2013, 54 isolates of group A streptococci (GAS) recovered from adult and pediatric pharyngeal specimens were randomly selected for testing against penicillin, erythromycin and clindamycin. As expected, all 54 isolates (100%) were susceptible to penicillin but, notably, only 65% of the GAS were susceptible to erythromycin and 69% were susceptible to clindamycin. In the past, this has appeared to correlate with increased use of erythromycin. As there can be cross-resistance between macrolides and clindamycin, there may not have been overuse of clindamycin.

Table 1 shows the comparative results of the antibiotic sentinel studies that were performed in 2007, 2009, 2011, 2012 and 2013.

As expected, all GAS isolates were susceptible to penicillin. However, an alarming and continued significant resistance to erythromycin and clindamycin was noted with only 52% and 50% of the GAS isolates tested susceptible to these respective antibiotics. Although erythromycin and clindamycin are the recommended antibiotics of choice for the treatment of GAS colonizations or infections in the penicillin-allergic patient, this astounding decrease in susceptibility makes treatment more difficult.

Group B streptococcal study results
A prospective antibiotic susceptibility prevalence study was performed on 60 randomly selected group B streptococci (GBS) recovered from vaginal specimens over a similar time period. Table 2 shows the comparative results for the sentinel studies conducted in 2007, 2009, 2011, 2012 and 2013.

Table 2 is the Comparative GBS Sentinel Study for 2007, 2009, 2011, 2012 and 2013

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Tuberculosis – An Old Disease With A New Test For Its Rapid Diagnosis

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

Tuberculosis (TB) is an infectious disease caused by Mycobacterium tuberculosis complex (Mtb). The disease has been with us for thousands of years and at one time developed resistance to human infection throughout recorded history and continues to be a significant cause of disease throughout the world today. With over two billion people (one-third of the world’s population) infected with Mtb, the World Health Organization (WHO) has declared TB as a “global health emergency.” Fortunately, 90% of individuals have latent or asymptomatic TB infection that will not go on to produce active disease. However, in certain instances, there may be transmission of disease to others. However, the remaining 10% of infected people will develop active or symptomatic disease. In years past, even though TB was regarded as a serious infectious disease, if diagnosed in the early, symptomatic stages of acute disease, these patients could be successfully treated with a combination of antitubercular drugs, such as isoniazid and rifampin, because Mtb had not yet developed resistance to these antibiotics. In 2011, the WHO estimated that there were 8.7 million new cases of active tuberculosis worldwide resulting in over 1.4 million deaths. In the early 1990s, TB was the leading cause of death in the U.S. Currently, the U.S. incidence of TB is at its lowest level since 1953. However, rapid and accurate diagnosis of TB continues to be a challenge, especially among immunocompromised patients and the elderly. For example, in 2011 alone, Mtb caused active disease in over 1.1 million HIV-infected patients worldwide resulting in over 430,000 deaths, making TB the leading cause of death in HIV-infected patients. According to the CDC, 63% of TB cases reported in the U.S. for the year 2012 were reported in foreign-born persons with case rates that were 11.5 times higher than among U.S. born individuals. Yet, any nationalty can fall victim to the disease. Returning U.S. travelers may also carry the disease and it can be just as deadly, especially if the Mtb strain causing the infection is multidrug resistant. TB most commonly causes pulmonary infections but almost any other organ system may become infected as well, though much less frequently. The symptoms of pulmonary TB in its early stages of acute disease are similar to many different types of respiratory infections. In the more advanced stages of disease, the patient typically experiences significant weight loss, night sweats, and a cough with the production of lower respiratory secretions, called sputum, which often contains blood. The advanced stages of TB can debilitate a patient to such an extreme extent that the disease was often called “consumption.”

Traditionally, the successful treatment of the early onset stages of active TB involved the use of combination antibiotic therapy with drugs, such as isoniazid and rifampin, as well as several others. Particularly, required when treating in the early stages of disease because Mtb isolates were typically universally susceptible to these antibiotics. However, with the widespread emergence of HIV infections in the late 1980s, the incidence of reactivated TB disease increased markedly in this patient group due to the underlying immunosuppressive nature of the HIV infection. As such, antitubercular therapies were used to treat these infections and, due to a host of reasons, some strains of Mtb eventually developed resistance to these agents. Currently, health authorities have estimated that, in 2011 alone, there were over 310,000 documented worldwide cases of multidrug-resistant tuberculosis caused by Mtb strains that were resistant to at least isoniazid and rifampin.

The diagnosis of active pulmonary tuberculosis is suspected based upon the signs and symptoms of the patient, the presence of a positive mycobacterial culture and/or evidence of a recent tuberculin skin test conversion or having a positive Quantiferon®-TB Gold In-Tube (interferon gamma release assay) test result. The diagnosis of TB is confirmed by performing confirmatory tests. Traditional tests involve the cultural recovery of Mtb from a clinical specimen, followed by its identification, and the performance of an antibiotic susceptibility test against the therapeutic agents normally used for treatment.

Since Mtb is a very slow-growing bacterium, the cultural recovery and identification of the organism is an extremely time-dependent process often requiring many weeks if not several months. As such, much time would pass before the clinician caring for the patient had laboratory information regarding the presence of Mtb in the specimen and whether the isolate was a multidrug-resistant strain. Patients infected with a multidrug-resistant strain of Mtb require intense and prolonged therapy with alternative, second-line antibiotic agents.

Within recent years, gene amplification technologies, such as polymerase chain reaction (PCR) assays, have been developed and used for detecting very small quantities of contaminating DNA and high reliability has been demonstrated as a significant advance in diagnostic infectious disease processes. The use of this technology has become commonplace in many clinical microbiology laboratories in the U.S. and throughout the world. Within the last few months, a new PCR test has been developed that detects the presence of Mtb-complex directly in clinical specimens and also screens for the presence of the spol gene mutation which is a surrogate marker for multidrug resistance. This new PCR assay can be completed within two hours of specimen receipt thereby informing the physician whether the patient is infected with Mtb that may or may not be multidrug-resistant prior to the clinician’s first encounter with the patient.

Laboratory Alliance’s Microbiology Department is currently the only laboratory in the Central New York area that offers this rapid PCR assay, which screens for Mtb directly in clinical specimens and determines whether the strain, if present, is multidrug resistant. The availability of this test will help eliminate physician guesswork and delays in the diagnosis of TB that will significantly improve patient outcomes by guiding appropriate therapy early in the course of patient management.

For more information, contact Dr. Granato at Laboratory Alliance at 315-461-5088 or by email to paulgranato@phdgenalysis.com.
Presentation Focused on Managing Millennials

Fourty-five Laboratory Alliance staff members from five sites, including vice presidents, directors, managers and supervisors, benefitted from a training session to learn more about the Millennial generation, also known as Generation Y. While there is not an exact age for this group, it includes those born roughly between the early 1980s and the early 2000s and is the fastest growing segment of today’s workforce.

The presentation focused on Millennial employees’ motives and values and highlighted ways employers can tap into their strengths, effectively communicate with and manage Millennial employees while guiding them to do their best.

“Millennial employees are motivated by relationships, and thus benefit from being managed differently than other generations,” says Adam Bidegary, a technical supervisor for specimen processing at ARUP Laboratories, who led the session at Laboratory Alliance’s Corporate Office on Sept. 18. “The Millennial generation is defined by work-life balance, multitasking and an integration of technology in all parts of life.”

“It was a phenomenal presentation,” Barbara Guiffrida, vice president of human resources, said. “Adam kept everyone’s undivided attention for nearly two hours.”

Due to staff who retire, move away or take a new job, Laboratory Alliance hires roughly 50 to 60 employees each year, with 45 to 55 percent in the Millennial age group.

Adam has 11 years of laboratory experience with six years of direct laboratory management and is working toward a Ph.D. in Industrial/Organizational Psychology. Along with his management responsibilities related to specimen processing and training, Adam has gained expertise in employee performance, error management, motivation, leadership development and process design and re-design.

ARUP Laboratories is a national clinical and anatomic pathology reference laboratory and an enterprise of the University of Utah and its Department of Pathology. ARUP has been Laboratory Alliance’s primary reference laboratory since 2002.
Thursday, Nov. 14 - Friday, Nov. 15
Clinical Laboratory Management Association and American Association for Clinical Chemistry Annual Conference and Exhibition, Turning Stone Casino Resort, Oneida. Laboratory Alliance is a flagship sponsor and exhibitor.

Monday, Nov. 18
Onondaga County Medical Society Annual Dinner Meeting at Holiday Inn, Liverpool. Laboratory Alliance is a corporate sponsor.

Saturday, Nov. 23
Upstate Gala at Nicholas J. Pirro Convention Center, Syracuse. Laboratory Alliance is a corporate sponsor.

Laboratory Alliance is encouraging anyone born between 1945 and 1965 to be tested for the hepatitis C virus. We are promoting this message in ads, on posters and in news releases to the media.

I’m asking my doctor for the Hepatitis C blood test

Were you born between 1945 and 1965?
It is recommended that baby boomers have a one-time screening for the Hepatitis C virus.

Hepatitis C is the leading cause of liver disease and liver cancer. Early diagnosis, determined by a laboratory blood test, can lower the risk of damage through monitoring and treatment.

Many baby boomers may have the virus and not know it.
Ask your doctor for the simple blood test today.

Laboratory Alliance was again recognized as a CenterState CEO Economic Champion at the Economic Champions Luncheon on Oct. 17. Each year we are honored for the role we play as an economic engine in the Central New York community.

Francis House is grateful for Laboratory Alliance’s continued support that included corporate underwriting, volunteers and generous employee contributions. This year our staff contributed more than $900 to the “No Place Like Home” raffle.

Enjoying the “No Place Like Home” fundraising event on Oct. 16 were (top photo) Malinda Desjardins, Kathy Shumway, Karl Lawton, Jane Riffanacht, Olga Farrell and Sue Maloney, and (bottom photo) Vickie Campany, Margie Grosick and Joan Rusin.

LABLines is a quarterly publication by LABORATORY ALLIANCE of CNY

Comments, suggestions or inquiries should be directed to Anne Marie Mullin Senior Vice President 315-461-3036, or by email to annemariemullin@lacny.com