New Strategies for Diabetes Testing — An Update

By Michael R. O’Leary, M.D., Chief Executive Officer, Director of Laboratories

The original article appeared in the Spring 2010 edition of LabLines. Diabetes is a group of metabolic diseases that affects 25.8 million Americans and can be explained very simply in the following example. When we eat food, our bodies break down sugars and starches into glucose, which is the basic fuel for all of our cells and tissues. The pancreas then secretes the hormone insulin which removes the glucose from the blood and moves it into cells and tissues. In the most common type of diabetes (95%), which is referred to as type 2 diabetes, either the body does not produce enough insulin or the insulin is ineffective in moving glucose into the cells. In either case, the resulting buildup of glucose in the blood, called hyperglycemia, often damages vital organs such as the kidneys, nerves and eyes.

For decades, the diagnosis of diabetes has been based on elevated blood glucose levels, measured either by the fasting glucose or the oral glucose tolerance test. Both require that the patient undergo an overnight fast, which can be a major inconvenience. In addition, fasting glucose levels often vary significantly in individuals, since they are dependent upon short-term dietary changes.

Due to the shortcomings of those tests, the American Diabetes Association’s new Clinical Practice Recommendations call for the addition of the hemoglobin A1C test as a means of diagnosing diabetes. This test has been used for years as a measure of how well people are doing in keeping their blood glucose levels under control. A1C is a marker of chronic hyperglycemia, reflecting average blood glucose levels over a two-to-three-month period of time. Currently, the test plays a critical role in the management of patients with diabetes. There is an inherent logic to using a more chronic versus an acute marker of hyperglycemia, particularly since A1C is already widely familiar to clinicians as a marker of glycemic control. Moreover, A1C has several advantages over the fasting glucose, including greater convenience since fasting is not required and there is less day-to-day variation of glucose levels. A1C is measured in terms of percentages and it measures a person’s average blood glucose levels over a period of up to three months.

Similar to previous recommendations, A1C levels consistently 6.5 % or greater should be used to make the diagnosis of diabetes. A1C levels of 5.7 – 6.4 % would indicate that blood glucose levels are in the prediabetic range, meaning higher than normal but not yet high enough for a diagnosis of diabetes. People with prediabetes have an increased risk of developing type 2 diabetes, heart disease and stroke.

The Centers for Disease Control estimate that 79 million Americans have pre-diabetes and that 40% of these will become fully diabetic in 3-8 years if untreated. The new standards also advise monitoring individuals with prediabetes on a yearly basis to prevent progression to full blown diabetes.

According to the Centers for Disease Control and Prevention (CDC), one-fourth of all Americans with diabetes, nearly 7 million people, do not even realize that they have it! The CDC hopes that the ease of the A1C test will facilitate identification of such individuals and facilitate their treatment. The American Diabetes Association emphasizes that the A1C test should be performed in a laboratory using a method that is certified by the National Glycohemoglobin Standardization Program (NGSP). Laboratory Alliance’s hemoglobin A1C method is NSGP-certified and is performed daily.

Next issue: Testing for Gestational Diabetes
Current Guidelines on HPV DNA Test Utilization
By John Fazio, M.D., Medical Advisor, Cytology Department

Since the publication of the American Society for Colposcopy and Cervical Pathology (ASCCP) 2012 Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests, the indications for performing high-risk (oncogenic) HPV DNA testing have changed. Accordingly, the College of American Pathologists (CAP) issued a statement in 2013 on HPV DNA test utilization, which is current and up to date (at least for now). This article will review the most important aspects of that statement. One thing the new guidelines focused on was risk/benefit ratio. Inappropriate or too frequent screening, including HPV testing, can lead to increased costs without proven benefit, and may cause patient harm by overtreatment.

High-risk HPV testing is appropriate in the following circumstances:

1. Routine cervical cancer screening in conjunction with cervical cytology (co-testing) for women ages 30–65 years. It is important to note that absent or insufficient endocervical/T-zone component is not an indication for early repeat cytology. When cytology and HPV results are both negative, both tests should be repeated only after a five year interval, and not sooner. Women who have negative cytology, but a positive HPV test, can either have repeat co-testing in 12 months (the more commonly used option), or they can have immediate genotyping for HPV 16/18. If this is positive, these women would go to immediate colposcopy, so this is a more aggressive option.

2. Initial triage management of women 25 years and older with a cytology result of atypical squamous cells of undetermined significance (ASC-US). For women ages 21-24, repeat cytology at 12 months without HPV testing is preferred.

3. Follow-up co-testing of women 25 years and older with preceding HPV negative ASC-US at three years. This is slightly more aggressive than the old guidelines, which called for a return to routine screening for HPV negative ASC-US.

4. Initial triage management of women ages 30 and older with low-grade squamous intraepithelial lesion (LSIL), generally when performed as part of a screening co-test. Only the HPV positive LSIL patients get colposcopy, while the HPV negative LSIL patients get repeat co-testing in 12 months.

5. Post colposcopy co-testing at 12 months for women 25 years and older, with either no lesion or CIN I and with a preceding “lesser” cytology result (i.e. ASC-US or LSIL).

6. Post colposcopy co-testing of women 25 years and older at 12 and 24 months, in those with either no lesion or CIN I when the preceding cytology result was a high-grade SIL (HSIL), or atypical squamous cells, cannot exclude HSIL (ASC-H). Alternatively, performing a diagnostic excisional procedure (such as a LEEP) is also acceptable in these patients.

7. Post colposcopy co-testing of women 21 years and older at 12 and 24 months, in those with no lesion or CIN I on colposcopy and preceding cytology result of atypical glandular cells, not otherwise specified (AGC, NOS). This is the only indication for HPV testing for women in the 21-24 age range.

8. Post treatment co-testing of women 25 years and older at 12 and 24 months with treated CIN II or III (“test of cure”).

High-risk HPV testing is generally not appropriate in the following circumstances:

1. Routine cervical cancer screening in women less than 30 years of age.

2. Routine cervical cancer screening with co-testing more often than every five years when previous co-test results were negative (and no prior abnormality).

3. Initial triage or management of women younger than 25 years with any cytologic abnormality.

4. Initial triage or management of women younger than 30 years with LSIL.

5. Initial triage or management of a woman any age with unsatisfactory cytology, ASC-H, HSIL, or atypical glandular cells of any type.

Other points made in the statement include the following:

1. Repeat high-risk HPV testing should generally not be done before 12 months.

2. Testing for low-risk (non-oncogenic) HPV types has no role in cervical cancer screening, or in the triage, management, or follow-up of women with abnormal cytology results.

3. Clinical judgement should always be used when applying a guideline to an individual patient, because it is impossible to develop guidelines that will apply to all situations.

This covers most of the current indications (and contraindications) of high-risk HPV testing, and it correlates with the ASCCP 2012 Consensus Guidelines.

For more information or to discuss any aspects of HPV testing, contact me at 315-492-5096 or by email to JohnFazio.ohpg@lacny.com, or our Cytology Department Manager Janet Miller at 315-410-7211.

Dr. John Fazio is with Onondaga Hill Pathology. P.C. and serves as a medical advisor to our Cytology Department. Dr. Fazio joined the pathology staff that practices at Upstate University Hospital Community Campus in 1993 and has served as a clinical instructor at SUNY Health Science Center in Syracuse, N.Y. He is board certified in anatomic pathology, clinical pathology and cytopathology.
CORRECT CODES ARE CRITICAL!

DID YOU KNOW?
Medicare may deny payment for a test even though the physician believed it was appropriate if the test did not meet Medicare’s definition of medical necessity.

NCDs and LCDs
National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) tests and information concerning appropriate diagnosis codes can be found on Laboratory Alliance’s website at laboratoryalliance.com under Healthcare Providers.

There, you will find:

• Specific test CPT codes for which medical necessity rules have been defined.

• The ICD-9 or diagnosis codes that Medicare will accept as documentation that the listed test is reasonable and necessary for diagnosis or treatment. ICD-9 codes supporting medical necessity must be included on the requisition form. The diagnosis must be present for the procedure to be paid and there must be documentation within the patient’s medical record.

Note: When ordering a test that does not meet NCD or LCD guidelines, an Advanced Beneficiary Notice (ABN) should be signed by 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 (i.e., signed) ABN.

Reflex Testing
Reflex testing is testing that is performed as a result of initial test results which are used to further identify significant diagnostic information required for appropriate patient care. A list of the reflex tests that are performed when appropriate is in our Directory of Services, on our website and on the back of our 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 included on our requisition and in our Directory of Services. Medicare reimbursement amounts 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.

Compliance Information was submitted by Nancy Sniffen, Director of Billing and Compliance, and Belinda Reed, Compliance Manager

• National Coverage Determinations (NCD) is a national policy statement that indicates which diagnoses, signs, or symptoms are payable for specific tests.

• Local Coverage Determinations (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. Our Medicare carrier is National Government Services.

• ICD stands for International Statistical Classifications of Diseases. ICD codes are alphanumeric designations given to every diagnosis, description of symptoms and cause of death attributed to human beings.

Your cooperation in providing diagnostic information is essential to the efficient operation of our lab. Without appropriate diagnostic documentation, we cannot get paid for our services.

Additionally, diagnostic information can determine whether or not an ABN should be signed. You can either provide an ICD-9 code or a written diagnosis in the space provided on the requisition.

Providing diagnostic information when ordering a test not only helps us operate efficiently and get paid for our services, it can also eliminate the time and expense the physician office may incur when reviewing files and responding to our requests.
As reviewed in the Winter 2014 issue of LabLines, septicemia, also called sepsis, is a serious, life-threatening immune response to infection in an individual’s bloodstream. Sepsis is associated with high mortality rates that, each year, account for over 200,000 deaths in the U.S. and millions more worldwide. Many microorganisms can cause septicemia including bacteria, viruses, fungi, and various types of parasites and protozoa, but most infections are caused by bacteria.

The bacteria that cause sepsis are generally divided into two major groups: 1) gram-positive bacteria; and, 2) gram-negative bacteria. Each of these bacterial species carry genetic determinants or markers that render them resistant to the action of certain antimicrobial agents that are often used for treatment. As such, the early recognition of the bacterial agent responsible for sepsis and knowledge of its susceptibility or resistance to certain antibiotics can have a decided impact on patient outcomes.

The laboratory diagnosis of sepsis is dependent upon the cultural recovery of the microorganism from the patient’s blood specimen. Conventional methods used for the characterization of bacteria recovered from a patient’s blood may require 1 to 2 days before its genus species identity and antibiotic susceptibility test results are available. More recently, an automated molecular assay employing the use of a multiplex, nucleic acid bead technology has been developed for the complete characterization of many bacteria responsible for septicemia as well as detecting the presence of genetic determinants that are responsible for antibiotic resistance. This molecular assay can be completed within 2 to 3 hours, thereby shortening the time for the generation of potentially life-saving laboratory results by 1 to 2 days.

Laboratory Alliance’s Microbiology Department now offers this molecular technology for the rapid characterization of bacterial isolates as part of its routine blood culture service. If a patient’s sepsis is caused by a gram-positive bacterium, the molecular assay will characterize 12 different bacterial groups including: Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunensis, Streptococcus anginosus, groups A and B beta hemolytic streptococci, Streptococcus pneumoniae, Enterococcus faecalis, and the genera Listeria, Streptococcus, and Staphylococcus. In addition, the assay screens for the presence of three antibiotic gene resistance markers associated with methicillin and vancomycin resistance. For gram-negative bacteria, the molecular assay will identify Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Proteus spp, Citrobacter spp., Enterobacter spp., Pseudomonas aeruginosa, and Acinetobacter spp. In addition, the assay will detect the presence of several different genetic determinants of resistance for bacteria that produce extended-spectrum beta lactamases (ESBLs). The assay will also detect the presence of gene markers for the production of carbapenemases that may be produced by certain members of the Enterobacteriaceae, called Carbapenem Resistant Enterobacteriaceae, also known as CREs or KPCs.

This new molecular technology will be offered 24 hours each day as part of Laboratory Alliance’s routine blood culture service. The rapid availability of this timely information will allow for the early administration of appropriate therapeutic care resulting in more favorable patient outcomes. Questions or concerns about this new molecular service can be emailed to me at paulgranatophd@lacny.com.
Sentinel antibiotic susceptibility prevalence studies for groups A and B streptococci are performed at least biannually by Laboratory Alliance's 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 recovered 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 March 27 to April 30, 2014, 50 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 50 isolates (100%) were susceptible to penicillin but, notably, only 84% of the GAS were susceptible to erythromycin and 90% were susceptible to clindamycin. In the past, this resistance has appeared to correlate with increased use of azithromycin. As there can be cross-resistance between macrolides and clindamycins there may not have been over-use of clindamycin. Since the percent of isolates susceptible is higher than 2013, the prescription use of macrolides may have decreased this year compared to the past two years.

Table 1 shows the comparative results of the antibiotic sentinel studies that were performed in 2007, 2009, 2011, 2012, 2013 and 2014.

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<th>Year</th>
<th>Antibiotic Tested (% Susceptible)</th>
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<td>Penicillin</td>
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The 2014 susceptibility patterns for erythromycin and clindamycin represented a decreased resistance than was detected for these antibiotics over the last sentinel study periods of 2013 and 2012 which had both shown increasing resistance to both macrolides and clindamycin.

The results of this limited sentinel study indicate that penicillin continues to be effective therapy for the treatment of GAS pharyngitis in the non-penicillin allergic patient and that erythromycin and clindamycin may be effective alternative therapeutic choices in the penicillin-allergic patient, but only when the results of susceptibility testing are available to verify the effectiveness of these drugs. This antibiotic susceptibility trend will be monitored and tracked by performing periodic sentinel studies.

**Group B streptococcal study results**

A similar antibiotic susceptibility prevalence study was performed on 50 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, 2013 and 2014.


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As expected, all GBS isolates were susceptible to penicillin. However, an alarming and continued significant increased resistance to erythromycin and clindamycin was noted with only 26% and 36% of the GBS isolates tested susceptible to these respective antibiotics. Although erythromycin and clindamycin are the recommended antibiotics of choice for the treatment of GBS vaginal colonization or infection in the penicillin-allergic patient, this astounding increase in resistance to erythromycin and clindamycin may be due to the increased use of these antibiotics to treat GBS colonized or infected patients who are not penicillin allergic.

If treatment is indicated for GBS, penicillin remains the agent of choice for intrapartum antibiotic prophylaxis in the non-penicillin allergic patient. Ampicillin is an acceptable alternative but penicillin is preferred because it has a narrower spectrum of activity and is less likely to select for bacterial resistance. Importantly, physicians are reminded that confirmed GBS resistance to penicillin has not been reported to date and, as such, antimicrobial susceptibility testing against this agent is not performed.

For penicillin-allergic women at risk for anaphylaxis, cefazolin, clindamycin, and erythromycin are possible therapeutic options as recommended by the Centers for Disease Control. While there is no GBS reported resistance to cefazolin, the results of this sentinel study show that only 26% and 36% of the GBS isolates tested were susceptible to erythromycin and clindamycin respectively. Since antimicrobial susceptibility testing is not routinely performed on GBS isolates, physicians may specifically request such testing when considering erythromycin or clindamycin as therapeutic options.

For more information, contact me by email at russellrawling@lacny.com.
Dr. O’Leary Prepares for Alma Mater Recognition

In preparation of an alumni award presentation at Siena College, Chief Executive Officer and Director of Laboratories Michael R. O’Leary, M.D., was interviewed for a video to air at the event in June. Dr. O’Leary received his bachelor of science from Siena College, located just north of Albany in Loudonville, N.Y. He will receive The Professor Joseph A. Buff Award recognizing alumni with outstanding accomplishments or achievements in their careers.

Dr. O’Leary’s career spans more than 35 years in laboratory medicine, including 16 years as Laboratory Alliance’s medical director. He received his medical degree from SUNY Upstate Medical University.

Siena College’s videographer and a member of the Communications Department visited and toured the Corporate Offices and Operations Center on April 28.

Employees Show Support of American Heart Association

Laboratory Alliance employees raised more than $5,000 for the American Heart Association this winter and 25 employees, plus their families and friends, participated in the Heart Walk/Run on behalf of the company. The 2014 Heart Walk was held on March 22 at Onondaga Community College. This is the second year the company has recognized a colleague who died in 2013 by wearing t-shirts marked with “In Memory of Barb Gonnella” in a heart on the back side.

Sovocool Appointed to ASCP Board of Governors

Michael L. Sovocool, MHS, PA(ASCP)CM was recently appointed a Member of the Board of Governors of the American Society for Clinical Pathology (ASCP). Mike, pictured right, is at work in the grossing process at our Rapid Response Laboratory at Crouse Hospital. He is an administrator and pathologist assistant with our affiliate pathologist practice, Pathology Associates of Syracuse. The ASCP’s Board of Certification is widely accepted as the most influential leader in certification of medical laboratory professionals.

Dr. Granato Presents at Florida Medical Meeting

Paul A. Granato, Ph.D., was a presenter at the Clinical Virology Meeting in Daytona, Fla. He was part of a panel that discussed “Herpes Viruses and Influenza: The Evolution of Detection and Real-Time Surveillance,” on April 28. The workshop-styled event discussed the latest advances in virus detection.
New Employees

Please welcome our new employees

At our Operations Center

- Kelly Costello – Phlebotomist
- Joseph Craver – Courier
- Jennifer Fasulo – Laboratory Office Assistant
- Joan Hantke – Phlebotomist
- David Hentges – Courier
- Corrin Mufale – Medical Technologist
- Jessica Spicer – Laboratory Office Assistant
- Thomas Torpy – Courier

At our Rapid Response Laboratory at St. Joseph’s Hospital

- Jessica Edick – Laboratory Office Assistant
- Jennifer Klein – Technical Processing Assistant
- Carrie Long – Medical Technologist
- Jarret Pend – Medical Technologist
- Corrinne Spaulding – Medical Technologist

Employee Anniversaries

April, 5 Years
- Elena D’Anna
- Melissa Ronk
- Roseanne Siefert
- Francis Springer, Jr.

April, 10 Years
- John Daucher
- Bonnie Larusso
- Sam Toscano

May, 5 Years
- Charles Mullane

June, 5 Years
- Jillian Stach

June, 10 Years
- Curtis Brunelle
- Sara Grimshaw

June, 15 Years
- Joni Ducey
- Dominick Frijo, Sr.

May is Skin Cancer Awareness Month

According to Randall A. Oyer, M.D., the medical director of the oncology program for Lancaster General Hospital in Lancaster, Pa., melanoma is on the rise and has been over the last 40 years.” Dr. Oyer discusses the topic in depth in his article, “Skin cancer awareness month puts spotlight on benefit of molecular diagnostics,” posted on the Lab Results for Life website at LabResultsforLife.org

“As we recognize May as Skin Cancer Awareness Month, we must also recognize that according to the American Cancer Society, 9,480 people are expected to die of melanoma by the end of this year,” he notes, adding, “That is unacceptable.”

Consider these important facts about skin cancer from WebMD:

- Skin cancer is the most common of all human cancers, with 1 million people in the U.S. diagnosed each year with some type of the disease.
- There are three major types of skin cancers: basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and melanoma. The first two skin cancers are grouped together as non-melanoma skin cancers. Other unusual types of skin cancer include Merkel cell tumors and dermatofibrosarcoma protuberans.
- The vast majority of skin cancers are basal cell carcinomas and squamous cells carcinomas. While malignant, these are unlikely to spread to other parts of the body. They may be locally disfiguring if not treated early.
- A small but significant number of skin cancers are malignant melanomas. Malignant melanoma is a highly aggressive cancer that tends to spread to other parts of the body. These cancers may be fatal if not treated early.
- Like many cancers, skin cancers start as precancerous lesions. These precancerous lesions are changes in skin that are not cancer, but could become cancer over time. Medical professionals often refer to these changes as dysplasia.
- Recent studies show the number of skin cancer cases in the U.S. growing at an alarming rate. Fortunately, increased awareness on the part of Americans and their health care providers has resulted in earlier diagnosis and improved outcomes.

For more information, visit LabResultsforLife.org or WebMD.com

Thanks, Lab Alliance

Laboratory Alliance employees contributed $350 to Hospice of CNY, money they raised during Laboratory Professionals Week by donating to ‘Wear Jeans to Work Day.’

Dillon Runs the Boston Marathon

Jacob Dillon, a materials handler at our Operations Center, ran his second Boston Marathon on April 21. A seasoned runner who has now completed five marathons, Jacob returned Boston to find a much more emotional experience. In 2013, he had just completed the marathon and was a few miles from the finish line when the bombs went off.

“This year was so much more meaningful, there was a much stronger sense of support,” Jacob said. “Last year it was exciting, a coveted experience that every runner strives for. But this year it was about the people, and with an additional 13,000 runners – a field of 36,000 – it was really special.”

Despite the hot sun and warm temperatures, Jacob shaved 12 seconds off his 2013 time, finishing the 26.2-mile race in 2:53!
CALENDAR OF EVENTS

Friday, May 30
St. Joseph’s Hospital Health Center Gala, Turning Stone Resort. Laboratory Alliance is a sponsor.

Wednesday, June 4
United Way of CNY Leadership Recognition Reception, The Hall of Fame at the Carmelo K. Anthony Center at Syracuse University. Laboratory Alliance is a sponsor.

Friday, June 20
Foundation for Upstate Towsley Pro-Am, Shenendoah Golf Club at Turning Stone Resort. Laboratory Alliance is a participant and sponsor.

Monday, July 14
Crouse Health Foundation Classic Golf Tournament, Bellevue Country Club. Laboratory Alliance is a sponsor.

Visit WebMD for Current Allergy News

As the weather warms up, allergy symptoms heat up as well. Web MD has a national Seasonal Allergy Symptoms tracker that reports the allergy levels by zip code. Simply type your zip code into the online tracker and allergy sufferers can see what they’re up against.

Visit symptoms.webmd.com/seasonal-allergy-map-tool. The website has links to many allergy topics.

Just because you don’t have symptoms doesn’t mean you don’t have hepatitis C

Born 1945-1965?
It is recommended you get a blood test for the hepatitis C virus. Many baby boomers got infected before the dangers of hepatitis C were well known.

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

Laboratory Alliance is running a series of ads, including this one, left, in local consumer and health care magazines and newspapers recommending that ‘baby boomers’ be tested for the hepatitis C virus. Nationally, a television ad campaign sponsored by Gilead Sciences is helping to bring awareness that more than 3 million people in the U.S. are living with this virus. Gilead sponsors a website offering more information on the disease at HepCHope.com.

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