

Screening Options for Gestational Diabetes Mellitus

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

Gestational diabetes mellitus (GDM) is one of the most common medical complications of pregnancy. Debate continues to surround the diagnosis of GDM despite several recent large-scale studies addressing this issue. There is little doubt that women with GDM are at higher risk of adverse pregnancy outcomes including large for gestational age birth weights, stillbirth and numerous neonatal morbidities, especially if maternal diabetes is poorly controlled.

Another important goal of GDM screening is identification of those women at risk of developing Type 2 diabetes, particularly those in high-risk ethnic groups such as Native American, African American and Latino. It is estimated that more than half of the pregnant population in the U.S. meet the criteria for early screening for diabetes including women with a basal metabolic index (BMI) ≥ 30 and a strong family history of diabetes.

As the ongoing epidemic of obesity and diabetes has led to more Type 2 diabetes, *not related to pregnancy*, in women of childbearing age, the number of pregnant women with *undiagnosed* diabetes has greatly increased. Therefore, it is reasonable to screen women with such risk factors for Type 2 diabetes at their initial prenatal visit.

GDM screening can be accomplished with either of two strategies:

1. "One Step": 2-hour Oral Glucose Tolerance Test (OGTT) using 75 gram glucose solution.
2. "Two Step": An initial 1-hour Glucose Load Test (GLT) using 50 gram glucose solution, followed by a 3-hour 100 gram OGTT *for those who screen positive*.

In 2011, the American Diabetes Association (ADA) recommended that all pregnant women not known to have prior diabetes undergo the "One Step" OGTT. Their recommendation was based on an International Association of Diabetes and Pregnancy Study Groups (IADPSG) consensus meeting. The ADA recommended this "One Step" screening due to the disturbing worldwide increases in obesity and diabetes rates.

The "Two Step" screening process has been promoted by the National Institutes of Health (NIH) and has been adopted by the American College of Obstetricians and Gynecologists. The "Two Step" process has the advantage of not requiring fasting for the initial screening test, and widely used in the United States.

A key factor reported in the NIH panel's decision-making process was the lack of clinical trial interventions demonstrating

Continued on page 2

Screening for and diagnosis of GDM

"One-step" (IADPSG consensus)

- Perform a 75-g OGTT, with glucose measurement at fasting and 1 and 2 h, at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes.
- The OGTT should be performed in the morning after an overnight fast of at least 8 h.
- The diagnosis of GDM is made when any of the following plasma glucose values are exceeded:
 - Fasting: >92 mg/dL
 - 1 h: >180 mg/dL
 - 2 h: >153 mg/dL

"Two-step" (NIH consensus)

- Perform a 50-g GLT (nonfasting), with glucose measurement at 1 h (step 1), at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes.
- If the plasma glucose level measured 1 h after the load is >140 mg/dL*, proceed to 100-g OGTT (Step 2).
- The 100-g OGTT should be performed when the patient is fasting.
- The diagnosis of GDM is made when the glucose level measured 3 h after the test is >140 mg/dL.

*ACOG recommends a lower threshold of 135 mg/dL in high-risk ethnic minorities.

IN THIS ISSUE

Page 2 Accessibility and Ease with New Website

Page 3 Dr. Huchzermeier Receives C of Q

Page 4 Dr. Granato Shares News from Microbiology

Page 5 Dr. Cobanov Joins St. Joseph's Pathology

Pages 6, 7 Employees in the News

Page 8 Calendar of Events

Laboratory Alliance Launches Its New Website

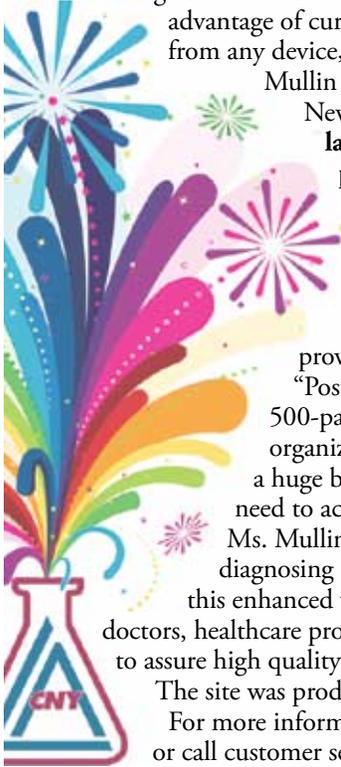
Following several months of development, Laboratory Alliance has gone live with a new, redesigned website that takes advantage of current web technology and accessibility from any device, Senior Vice President Anne Marie Mullin said.

New features on the website, www.laboratoryalliance.com, include a patient service center finder linked to Google maps, a laboratory test directory with detailed specimen collection information for healthcare providers, an online employment application and links to patient and provider information.

“Posting the contents of our nearly 500-page *Directory of Services* online in an organized and easy-to-access format will be a huge benefit to healthcare providers who need to access this information on a daily basis,” Ms. Mullin said. “Laboratory tests are vital to diagnosing and treating illness and disease, and this enhanced website is another service we can offer doctors, healthcare providers and Central New York patients to assure high quality healthcare.”

The site was produced by Syracuse Design Group.

For more information, visit laboratoryalliance.com or call customer service at 315-461-3008.



Gestational Diabetes Mellitus

Continued from page 1

the benefits of the “One Step” strategy. Additionally, screening with a 50 gram glucose load test does not require fasting and is much easier to accomplish for many women.

The conflicting recommendations from these two key consensus panels are baffling, but underscore several key points:

1. There are insufficient data to strongly demonstrate the superiority of one strategy over the other.
2. There are a number of currently unmeasured factors such as cost-benefit estimation, clinical intervention trial results and role of cost considerations which would be helpful in deciding which strategy to implement.
3. Further research is needed to resolve these uncertainties.

However, there remains a strong consensus that establishing a *uniform* approach to diagnosing GDM will have significant benefits for patients, caregivers and policy-makers. Fortunately, longer-term outcome studies are currently underway.



Working together for the health of our community

Laboratory tests are vital to assess wellness and to diagnose and treat illness and disease.

We're grateful for the role we play in providing Central New York with the highest quality healthcare.

When you need lab tests, visit laboratoryalliance.com.

Then visit one of our 11 Patient Service Centers in your neighborhood:

In East Syracuse, visit us in the Brittonfield Medical Center
5000 Brittonfield Pkwy, Suite A108

8:00 am - 4:30 pm
Closed for lunch 12:15-1 pm

We're also in Baldwinsville, Camillus, Cazenovia, Cicero, Fayetteville, Liverpool, Pulaski and 4 locations in Syracuse.





Director of Assay Development Receives Certificate of Qualification

By Anne Marie Mullin, Senior Vice President

Roy Huchzermeier had an affinity for the laboratory long before he obtained his doctorate in biochemistry. His part-time job was drawing blood and performing lab tests in the laboratory at St. Joseph's Hospital Health Center while he was earning degrees from SUNY ESF and Syracuse University. Fast-forward 30 years where he is still doing laboratory work, serving as the accomplished head of Laboratory Alliance's Assay Development team.

Dr. Huchzermeier's long and prestigious career in laboratory science earned him his most recent accomplishment, the Certificate of Qualification (C of Q) from the New York State Department of Health. He is qualified to act as a Laboratory Director in the categories of Clinical Chemistry and Therapeutic Substance Monitoring/Quantitative Toxicology.

Certification requires an extensive resumé of laboratory experience combined with a doctorate in hard science. Dr. Huchzermeier has both.

After earning his Ph.D., he worked nine years at St. Joseph's Hospital Health Center before heading to Abbott Laboratories in North Chicago, where he was the project manager for developing the TDX T-Uptake Thyroid Assay. His interest in research and development led him to make significant achievements from coast to coast. Dr. Huchzermeier worked on products and methods at Roche Diagnostics and Ortho Diagnostic Systems, both in New Jersey, before going to Ciba Corning Diagnostics in Massachusetts. This was followed by employment at Miles Diagnostics in New York, and Diagnostic Products Corporation in California. He found his way back to Syracuse in 1994, where he founded and became CEO of Syracuse Bioanalytical, Inc. Laboratory Alliance utilized Dr. Huchzermeier's chemistry expertise in a consultant capacity for several years before he officially joined the company in 2012.

The motivation behind Laboratory Alliance's efforts to develop assays as opposed to using outside vendors is primarily cost savings.

"We evaluate assays that we send out to national laboratories and when it makes sense to bring them in house, we proceed with development using strict requirements," Dr. Huchzermeier said. "Each test we develop takes in the neighborhood of eight months to a year, three quarters of that time developing the method and optimizing conditions. Then we put the assay through its paces in the validation phase, where it undergoes numerous tests."

All of this data goes into an extensive report before receiving approval by New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP). CLEP is based at the state's Wadsworth Center, a science-based community in Albany, N.Y., committed to protecting and improving the health of New Yorkers through laboratory analysis, investigations and research, as well as laboratory certification and educational programs.

The assay development process sometimes involves international collaboration. An example of this is an LC-MS/MS assay for methylmalonic acid which was developed through collaboration with Dr. Albena Mihailova of Oslo, Norway. Her department at Akershus University Hospital shared their expertise and experience during our development and implementation. New York State Department of Health CLEP approval was granted.

About a year ago, Laboratory Alliance began offering in-house liquid chromatography tandem mass spectrometry (LC-MS/MS) testing for serum testosterone in women and children. This LC-MS/MS assay was developed by Dr. Huchzermeier and his team. "This new in-house assay represents a state-of-the-art methodology utilized by major reference laboratories and offers rapid turnaround times not available from other local medical laboratories," said Michael O'Leary, M.D., CEO and director of laboratories.

Read more about the development of this test in the article, "Serum Testosterone in Women/Children by Liquid Chromatography Tandem Mass Spectrometry," published in our Spring 2013 issue of *LabLines* and available on our website: visit laboratoryalliance.com and select "About Us" then "Company Profile." Select the Spring 2013 newsletter, which can be viewed in a PDF format.

Dr. Huchzermeier and his team have started work on a confirmatory assay of cannabinoids (marijuana) that they hope to bring in-house by years end. With 10 patents and patent-pending applications, and his new C of Q certification, his expertise is strongly valued by Laboratory Alliance.



Roy Huchzermeier, Ph.D.



For more information, Dr. Huchzermeier is available by email at royhuchzermeier@lacny.com



News from the Microbiology Department

Molecular Technology for the Rapid Diagnosis of Sepsis

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

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.

Welcome to our New Clients

Upstate New York Eating Disorder Service
Ophelia's Place
Syracuse, N.Y.

Syracuse Midwives
Syracuse, N.Y.

Insource Urgent Care
Auburn, N.Y.

Dr. Padma Ram Medical Services LLC
Oswego, N.Y.

April Ward, CNM
Syracuse, N.Y.

Technology Corner

The following new tests and test methods have been added to the menu of tests performed by Laboratory Alliance:

Rapid Combo HIV Screen: 4th generation test for detection of antibodies to HIV1, HIV2 and/or HIV p24 antigen

For more information about laboratory testing, visit **Lab Tests Online** at labtestsonline.org. We recommend this "peer-reviewed, patient-centered, outcomes-driven website" as it serves as a public resource on clinical lab testing from the laboratory professionals who do the testing.

A Conversation with Dr. Cobanov

By Anne Marie Mullin, Senior Vice President



Brando Cobanov, M.D.

University School of Medicine in California. I then completed a pathology residency at Robert Wood Johnson Medical School in New Brunswick, New Jersey. During my residency Robert Wood Johnson was part of the University of Medicine and Dentistry of New Jersey. It is now part of Rutgers, the State University of New Jersey.

Anne Marie: So, you're a Los Angeles native and you find yourself on the east coast?

Dr. Cobanov: Having grown up in California, I wanted to explore other parts of the United States. Following my residency in New Jersey, I completed a one-year Oncologic Surgical Pathology fellowship at Memorial Sloan-Kettering Cancer Center in New York City. During my time there I saw a wide array of complex and interesting cases. I then did a second fellowship in cytopathology at the University of Pennsylvania in Philadelphia. Not only did I gain valuable experience during my training, but I also was able to live in different cities.

Anne Marie: How did you select the pathology practice at St. Joseph's Hospital?

Dr. Cobanov: I was working in Fort Wayne, Indiana, in a private pathology practice that was affiliated with a hospital system, much like St. Joseph's Pathology, PC. Having enjoyed my time on the East Coast, I wanted to relocate there if the opportunity presented itself. When a position opened in Syracuse, my wife and I were happy to move, placing us closer to relatives in Massachusetts. I feel fortunate to be part of a great practice and hospital system.

Anne Marie: When you're not at work, how do you spend your free time?

Dr. Cobanov: I have a five-year-old son and a one-year-old daughter. As you can imagine, they keep my wife and me quite busy. We are getting to know Syracuse and the surrounding area. We enjoy traveling and spending time with family. When I have some spare time, I enjoy playing tennis and have recently taken up golf.

Dr. Cobanov is board certified in Anatomic and Clinical Pathology as well as Cytopathology. He can be reached at St. Joseph's Pathology PC and at brandocobanovmd@lacny.com

I recently spoke with Dr. Brando Cobanov of St. Joseph's Pathology PC of Syracuse, located at St. Joseph's Hospital. Dr. Cobanov joined the practice on June 2.

Anne Marie: What made you decide on a career in pathology?

Dr. Cobanov: The investigative nature of pathology has always interested me. With all the advances in genetics and cell biology in recent years, it is a very exciting time to practice pathology. I attended Loma Linda



Dr. Cobanov, pictured here with Anne Marie Mullin, is board certified in Anatomic and Clinical Pathology as well as Cytopathology. He can be reached at St. Joseph's Pathology and at brandocobanovmd@lacny.com.

Urgent Appeal for Blood Donation

The Red Cross has issued an urgent appeal for blood donations to prevent an emergency shortage and to ensure an adequate blood supply this summer.

The American Red Cross is asking for our help. With fewer blood donations than expected in the past 11 weeks, there is an urgent need for donors of all blood types to roll up a sleeve and give.

To prevent an emergency shortage and to ensure an adequate blood supply for patients, the Red Cross especially needs platelet donors and those with types O negative, B negative and A negative blood to give.

Those eligible to give blood or platelets can make an appointment online at redcrossblood.org or by calling 1-800-RED CROSS (1-800-733-2767).

Donations will help replenish the blood supply and ensure that blood continues to be available for patients with serious medical needs all summer long.

To schedule an appointment at the Blood Drive sponsored by Laboratory Alliance on Thursday, Aug. 14, please contact Marsha Herbst at marshaherbst@lacny.com.



Blood Drive
Thursday, Aug. 14
9 a.m. – 2 p.m.

1304 Buckley Rd., Suite 300
Schedule your appointment today
315-461-5903 or
marshaherbst@lacny.com

In The News

Dr. Granato Delivers Presentations, Published Articles



Paul A. Granato, Ph.D., director of microbiology, had his letter to the editor on Direct Stool EHEC Testing published in a recent issue of *Medical Laboratory Observer*.

In May, Dr. Granato presented a talk on “Herpes Simplex Virus: Clinical Diseases and Update on Improved Methods for Laboratory Diagnosis” at the Southeast Association for Clinical Microbiology (SEACM) held in Charlotte, N.C.

Also in May, he gave an invited presentation at the General Meeting of the American Society for Microbiology on “The Laboratory Diagnosis of Sepsis: Past, Present, and Future.” The meeting was held May 17-20 in Boston, Mass.

Along with co-author **Brenda R. Alkins**, molecular specialist in Laboratory Alliance’s Microbiology Department, Dr. Granato had his scientific study titled “Multicenter Evaluation of the Quidel Lyra direct

Clostridium difficile Nucleic Acid Amplification Assay” published electronically ahead of print in the March 26 issue of *Journal of Clinical Microbiology*.

Finally, Dr. Granato was notified in July that his abstract for the Association for Molecular Biology’s AMP 2014 Annual Meeting has been accepted for both Poster Presentation and publication in *The Journal of Molecular Diagnostics*. His abstract, titled “Comparison of AmpliVue GBS Assay with GeneXpert GBS Assay and Culture for Detecting Group B Streptococci in Vaginal/Rectal Specimens Following Lim Broth Enrichment,” is in the Infectious Diseases category. The AMP 2014 Annual Meeting will be held Nov. 13-15 outside Washington, D.C.

Laboratory Alliance Sponsors United Way Reception

United Way held its Leadership Reception in early June at the Carmelo Anthony Hall of Fame Center at Syracuse University. Along with being recognized as a leadership donor, Laboratory Alliance was a corporate sponsor. Senior Vice President Anne Marie Mullin attended with CEO and Medical Director Dr. Michael R. O’Leary and his wife, Dr. Colleen O’Leary. Pictured below, left to right, are United Way of Central New York’s President Frank Lazarski and his wife Denise, Anne Marie Mullin, Dr. Michael O’Leary and United Way’s Director of Leadership Development Marianne Ferris.



Drs. Colleen and Michael R. O’Leary

Siena College Salutes Its Own at Alumni Event

CEO and Director of Laboratories Michael R. O’Leary, M.D., was honored by his alma mater Siena College with The Professor Joseph A. Buff Award recognizing alumni with outstanding accomplishments or achievements in their careers. He and his wife, Dr. Colleen O’Leary, attended the Distinguished Alumni Awards Ceremony during Reunion Weekend 2014 held at the college June 6-8.

Dr. O’Leary’s career spans more than 35 years in laboratory medicine, including 16 years as Laboratory Alliance’s medical director. Dr. O’Leary received his bachelor of science from Siena College, located just north of Albany in Loudonville, N.Y. He received his medical degree from SUNY Upstate Medical University.

LA Newsmakers

New Employees

Please welcome our new employees

At our Operations Center

Jeffrey Burgess – Courier

Mark Jordan – Research and Development Specialist

Jeffrey Sanderson – Courier

At our Rapid Response Laboratory at Crouse Hospital

Don Massey – Medical Laboratory Technician

Ben Robedee – Medical Technologist

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

Kaitlyn Diaferio – Medical Laboratory Technician

Julie Smithers – Medical Technologist

Matthew Sullivan – Medical Technologist

Employee Anniversaries

July, 15 Years

Dawn Nappa

August, 15 Years

Li Chen

Lisa Gilbert

David Mineo

September, 5 Years

Kimberly Kemp

Jacqueline Lowe

Celeste Nelson

Tina Pride-Williams

Laboratory Alliance Provides Triathlon Pace Car, Courier Volunteers Time

Laboratory Alliance provided the pace car and driver for the 35th Green Lakes Triathlon, held June 7 in Fayetteville, N.Y.



Courier Michael Manfredi, right, joined race director Chris Read, center, and founding race director Walt Price, left, before the start of the event.

The Green Lakes Triathlon is the oldest continuous running triathlon in the United States and is a certified Livestrong event. Walt Price was also the founding director of the Mountain Goat Run as well as the Folksmarch walking club.

“I was glad for the opportunity to have Walt ride in the pace car with me,” said Mike. “He said that he never thought that his Mountain Goat run would have grown into thousands of people running through the streets of Syracuse, with prize money being offered to the winners.”

Mike also learned that Walt, while visiting his daughter in Germany, saw that communities would gather socially for fitness walks. When he came back to Syracuse he decided to start a Folksmarch walking club here.

Price came to Syracuse in 1955 to take the Regional YMCA directors position. Chris Read now directs the Triathlon, but Price is still active in the planning as well as his Folksmarch program and other programs at the YMCA.

This is the second year that Laboratory Alliance has provided the car and Mike has volunteered his time for the event.

Kathleen Shumway Among Search and Rescue Team Graduates

Kathleen K. Shumway, business applications manager at our Corporate Offices, graduated in June from Oswego County Search and Rescue Team's three-month Training Academy. She is pictured

with the group of graduates in the front row, fourth from left. Training involved one weekly three-hour class and several Saturday practices covering topics such as map and compass, global positioning systems, man-tracking, wilderness survival, radio communications and more. She will volunteer for the organization, which is dispatched through the county's 9-1-1 system and is recognized as a public safety agency.



COMMUNITY CONNECTIONS

CALENDAR OF EVENTS

Friday, Sept. 5

St. Joseph's Hospital Health Center 22nd Annual Golf Classic, Turning Stone Resort. *Laboratory Alliance is a corporate sponsor.*

Saturday, Sept. 13

Laboratory Alliance Company Clambake, The Spinning Wheel Restaurant. Employees should sign up by Wednesday, Sept. 3.

Friday, Sept. 19

September Song to benefit Hospice of CNY, Traditions at the Links.

Friday, Sept. 19

2014 Tribute Evening to benefit Crouse Hospital Foundation, The Oncenter. *Laboratory Alliance is a corporate sponsor.*

Wednesday, Oct. 15

"There's No Place Like Home" event to benefit Francis House, New York State Fairgrounds.

september song

Celebrate a legacy of caring!

Cheers to 25 Years!

For 25 years, Central New Yorkers attending September Song have raised the money needed to offer comfort care for thousands of terminally ill patients and their families

Join us Friday, September 19th
from 6pm to 10pm at
Traditions at the Links at Erie Village
\$125 per person
Tables of 10 for \$1,000

Call 315-634-1100 to make your reservation!

We're pleased to announce the launch of our new website

Look at us now!

Log on to **LaboratoryAlliance.com** and see why we're excited. **LaboratoryAlliance.com** is easy to navigate, takes full advantage of current web technologies, and it's accessible from any device.

Turn to **LaboratoryAlliance.com** for Patient Service Center hours and directions, to look up a test or to access our *Directory of Services*, and for other information you seek, quickly and with ease.

We welcome your feedback and look forward to serving you online, on the phone or in person with your laboratory and healthcare needs.

Visit **LaboratoryAlliance.com** or call Customer Service at 315-461-3008.



LABlines

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