



Helicobacter pylori – Overview and New Test Guidelines for Diagnosis

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

New Test Guidelines

Helicobacter pylori is one of the most common bacterial infections worldwide. Serologic antibody tests have been the traditional mainstay for diagnosing *H. pylori* infection because of the convenience in specimen collection.

However, in recent years, it has been repeatedly demonstrated that these antibody tests have poor sensitivities in distinguishing between active and past infection and cannot be used reliably to evaluate patients for test of cure (TOC). As a result, the American Gastroenterology Association (AGA) and the American College of Gastroenterology (ACG) no longer recommend the routine use of these serologic tests. Instead, they recommend the *H. pylori* stool antigen test (SAT) or the urea breath test (UBT) for diagnosis and evaluating patients for TOC. Because of these updated AGA and ACG guidelines and the documented poor sensitivities of the serologic tests, many insurance carriers have implemented policies whereby they will no longer reimburse for *H. pylori* serologic tests. In addition, many reference laboratories have discontinued *H. pylori* serologic testing as a diagnostic service. This brief article serves as an overview of the diseases caused by *H. pylori* and the available invasive and non-invasive tests that can be used for reliably establishing its diagnosis and determining TOC.

Discovery and the Nobel Peace Prize

Prior to the 1990s, traditional medical convention and dogma attributed certain lifestyles, such as alcohol abuse, physical and emotional stress, and smoking as the cause of gastritis and peptic ulcer disease (PUD). In the early 1980s, two Australian physicians, Robin Warren, a pathologist, and Barry Marshall, a gastroenterologist, thought that gastritis and PUD were caused by an infectious agent. Warren had noted the histologic presence of curved bacteria and an associated inflammatory response in stomach biopsy specimens collected from patients with gastritis and PUD. Marshall attempted to grow this organism in the laboratory but was unsuccessful after many repeated attempts. Then, over an extended Easter holiday, the microbiology laboratory accidentally held some of the culture plates for five days instead of the usual two. This serendipitous act due to an extended

incubation period resulted in the cultural recovery of the bacterium from the specimens. Because the bacterium had a curved or spiral-shaped morphology resembling bacteria in the *Campylobacter* genus, the bacterium was initially called a *Campylobacter*-like organism (CLO) or *Campylobacter pyloridis*. Subsequently, based upon extensive genetic analyses and DNA homology studies, the organism was taxonomically positioned into a new genus, *Helicobacter*, and designated *H. pylori*.

Excited about their findings that gastritis and PUD were caused by an infectious agent, Marshall and Warren reported their results in two medical publications (Lancet. 1983. 321: 1273-1275, Lancet. 1984. 323: 1311-1315). Unfortunately, their proposal that gastritis and PUD were caused by an infectious agent was met with considerable skepticism and ridicule from the medical and scientific communities because it was not thought that any bacterium could survive in the harsh acidic environment of the stomach to cause disease.

Continued on page 6

Dr. Graber Named Medical Director



Laboratory Alliance welcomes Michael W. Graber, M.D., as medical director of our Operations Center laboratory.

Dr. Graber has been affiliated with Laboratory Alliance since 2001, most recently as assistant medical advisor of Transfusion Services and assistant medical director of the rapid response laboratory at Upstate University Hospital Community Campus.

Board certified in anatomic pathology, clinical pathology and hematopathology, he is employed by Onondaga Hill Pathology, P.C. and is a staff pathologist at Upstate University Hospital Community Campus. He will continue to practice anatomic pathology at Laboratory Alliance's rapid response laboratory at Upstate University Hospital Community Campus in addition to serving as medical director of the Operations Center.

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The Paris System for Reporting Urinary Cytology

By John Fazio, M.D., Medical Director, Cytology Department

There is a new standardized terminology system for urinary cytology and it is called “The Paris

System for Reporting Urinary Cytology”. This system represents an international consensus, with input from cytopathology and urology experts throughout the world.

One of the issues this system tried to address is the fact that urinary cytology is not very good at detecting low grade papillary urothelial neoplasms. This is not surprising, considering that these lesions do not shed cytologically malignant cells, and that most of these lesions are not true cancers in the traditional sense, in that they do not metastasize or kill patients who have them. However, urinary cytology is very good at detecting high-grade urothelial carcinomas as well as urothelial carcinoma in situ, which are truly aggressive life-threatening lesions. Recognition of these lesions is especially beneficial to patients whose bladders may appear endoscopically normal. Low-grade urothelial neoplasms, by contrast, are easily detected by experienced urologists and are not aggressive, so the inability of cytology to detect these lesions is not a significant problem. Urinary cytology is the only non-invasive method that can distinguish low-grade lesions from high-grade urothelial carcinoma, and for that reason is highly relevant to patient care.

The main goal of urinary cytology is the detection of urothelial carcinoma that is clinically significant, namely high-grade urothelial carcinoma. Therefore, the guiding principle for the Paris System is to detect high-grade urothelial carcinoma (HGUC). In line with this principle, the negative category includes reactive changes, infectious and non-neoplastic conditions, as well as some cases that may have some cytologic features of low-grade urothelial neoplasms, but are negative for high-grade urothelial carcinoma (HGUC). Therefore, the proposed diagnostic category is “Negative for High-Grade Urothelial Carcinoma” (NHGUC). This is a huge improvement over the old system, where the cytopathologist was forced to report

“atypical cells present” if there were cells which might be due to a low-grade urothelial neoplasm, but there was clearly no evidence of a high-grade urothelial carcinoma. This new reporting system should significantly decrease the number of urine cytology specimens signed out as “atypical”.

In the Paris System there are categories of “Atypical Urothelial Cells” (AUC) and “Suspicious for High-Grade Urothelial Carcinoma” (SHGUC). These categories are meant to denote the presence of cells that have some, but not all, of the features of high-grade urothelial carcinoma. Although the diagnosis of low-grade urothelial carcinoma is not the main goal of this system, a separate diagnostic category has been included to define those circumstances where cytologic features of low-grade urothelial neoplasms are present. Only in the presence of three-dimensional cellular papillary clusters with fibrovascular cores (including capillaries) is a definitive cytologic diagnosis of low-grade urothelial neoplasm (LGUN) possible. A diagnosis of LGUN could include urothelial papilloma, papillary urothelial neoplasm of low malignant potential (PUNLMP), low-grade papillary urothelial carcinoma, and flat low-grade intraurothelial neoplasia (dysplasia).

The Paris System attempted to tackle the issue of adequacy of urine specimens. Adequacy is a source of disagreement and controversy in all areas of cytopathology, and urinary tract specimens are no exception. Numerous pre-analytical specimen variables may influence the performance characteristics of urinary tract cytology and may confound adequacy determination. These variables include, but are not limited to collection type, cellularity, and volume. These variables, in conjunction with the final diagnosis and the presence or absence of obscuring features, were used to construct an adequacy algorithm. Detailed discussion of this algorithm is beyond the scope of this discussion, but suffice it to say that minimal cellularity and/or specimen volumes were attempted to be defined for urinary specimens. It goes without saying that the presence of any atypical, suspicious, or malignant findings automatically makes the specimen adequate, regardless of cellularity, volume, or other variables.

The category of atypical urothelial cells (AUC) is meant to fill the gap between what can be recognized as entirely normal and what can be recognized as being clearly abnormal. The general diagnostic category of AUC is reserved for specimens that contain urothelial cells with mild to moderate cytologic (not architectural) atypia. This definition does not include urothelial cell clusters (tissue fragments) without cytologic atypia, which belong in the negative for high-grade urothelial carcinoma (NHGUC) category. To be classified as AUC, the cytologic changes have to fall short of suspicious for high-grade urothelial carcinoma or positive for high-grade urothelial carcinoma. In addition, this category requires exclusion of changes in which the reason for “atypia” is known, such as reactive changes due to infections, stones, instrumentation, etc. The AUC category also includes specimens where, due to poor preservation and degenerative changes, the nature and degree of atypia in the urothelial cells cannot be well analyzed.

Lastly, the diagnosis of suspicious for high-grade urothelial carcinoma (SHGUC) is meant to reflect the presence of urothelial cells with severe atypia that fall short of a diagnosis of high-grade urothelial carcinoma (HGUC), but beyond atypia that is associated with the “atypical urothelial cells” (AUC) category. The diagnosis is restrictively used in cases that quantitatively fall short of a diagnosis of HGUC. A cut-off range of 5-10 cells is recommended based on the degree of abnormal nuclear changes observed and the level of the pathologist’s comfort.

The Paris System attempted to standardize the diagnostic criteria and bring uniformity to the diagnostic reporting of urinary cytology specimens. It is a vast improvement and should prove very useful to clinicians taking care of patients with urinary tract disease.

Please do not hesitate to contact me at 315-492-5096 or Janet Miller, Cytopathology Manager, at 315-410-7210, if you have any questions or concerns about this new reporting system.

Reference: Rosenthal D, Wojcik E, Kurtycz D (Eds). The Paris System for Reporting Urinary Cytology. New York: Springer; 2016.

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-10 or diagnosis codes** that Medicare will accept as documentation that the listed test is reasonable and necessary for diagnosis or treatment. ICD-10 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/ClinicalLabFeeSchd/. Medicaid reimbursement will usually be equal to or less than the Medicare reimbursement.

Clinical Consultation Services

Appropriate test use and ordering may be discussed with Laboratory Alliance's Medical Director Michael Graber, M.D., available by contacting our Customer Service Department at 315-461-3008.

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-10 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's office may incur when reviewing files and responding to our requests.

- **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.

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

Introducing our Microbiology Department



Laboratory Alliance's Microbiology Department staff of 40, including full- and part-time, provide services to Crouse, St. Joseph's and Upstate University Community Campus hospitals, reference lab clients and our physician clients and their patients.

Located at our Operations Center, it is in this department that tests for sexually transmitted infections (STIs), urinary tract infections (UTIs), enteric pathogens, sepsis, respiratory infections, strep throat, flu, bacterial pneumonia and more. The department also participates in clinical device trials for new assays and instruments related to infectious disease.

Operating around the clock seven days a week, our microbiologists are New York state licensed, many also certified by the American Society of Clinical Pathologists and participate annually in national proficiency testing and continuing education activities.

Director of Microbiology Paul A. Granato, Ph.D., and Microbiology Manager Russell Rawling oversee the department.

In the top photo, from left, are Johnathan Daddario, Beth Denny, Jennifer Lillie, Michael Badner and Miranda Masterpol.

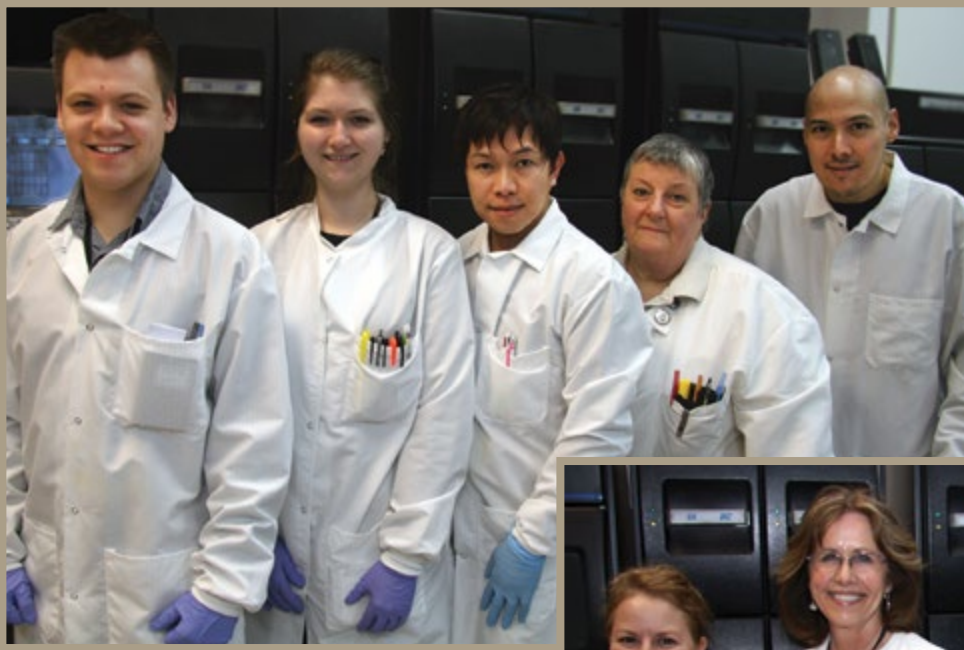
Pictured left are Jeremy Fuller, Rebecca Reynolds, Brian Meaker, Katrina Zeglin, Li Chen and Andrea Bertolero.



Pictured right are Elsie Wilson, Marcia Degilio, Linda Stallcup and Dr. Paul Granato.

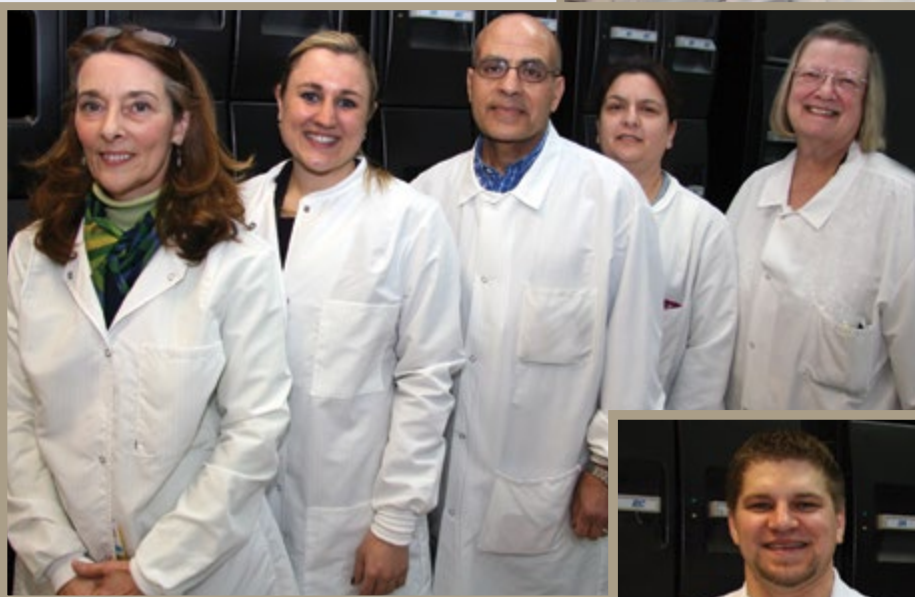


Laboratory Alliance is ready to offer challenging and rewarding career opportunities to qualified candidates. Our team of more than 400 professionals performs over 10.7 million laboratory tests annually. Consider a career with the area's largest laboratory. Apply online at laboratoryalliance.com/careers



Microbiology Department professionals pictured left are Corey Rivet, Melissa Carter, Ronilo Aquino, Karen Strouse and Brian Monterosso.

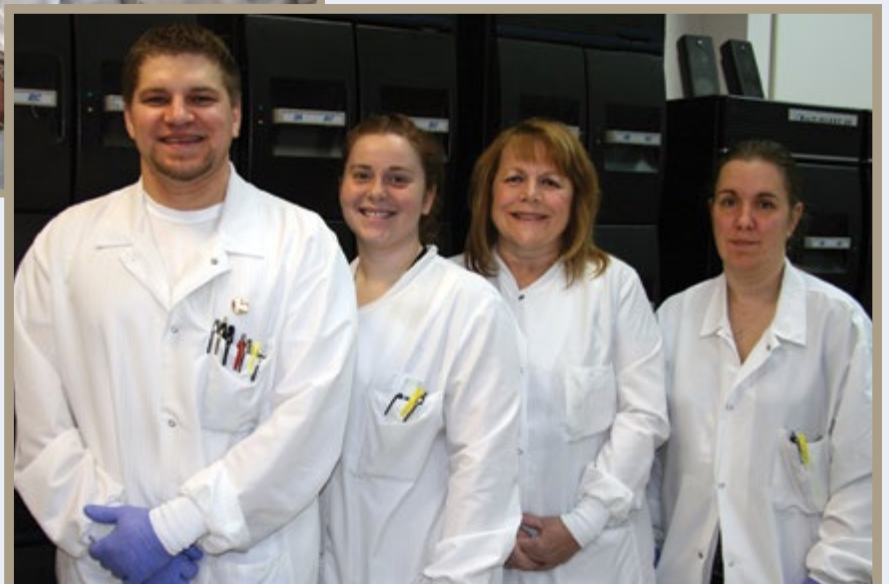
Below, from left, are Cristina Lenartowicz, Jane Roller, Celeste Nelson, Manager Russell Rawling and Brenda Henry.



In the photo above, from left, are Nancy Tucci, Melissa Unz, Karim Galal, Laura Buehler and Janet Kerfien.

Pictured right are Keith Rando, Megan Talbot, Martha Stewart and Dolores Juliano.

The following microbiology staff members were not available for a photo: Brenda Alkins, Melleny Hale, Dawn Nappa, Shannon Nayyar, Nadine Riche, Ellen Searles and Erin Springer.



Helicobacter pylori – Overview and New Test Guidelines for Diagnosis

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Frustrated by the scientific and medical rejection of their findings, Barry Marshall recovered *H. pylori* from a patient with PUD, grew it in the laboratory in a liquid broth culture, and then drank it. Several weeks later, he developed symptoms of gastritis which is a precursor of PUD. A biopsy was taken from Marshall's stomach by endoscopy which showed histologic evidence of inflammation and the presence of curved bacteria in the tissue. Furthermore, the same *H. pylori* was recovered by culture thereby fulfilling Koch's postulates and establishing *H. pylori* as a cause of gastritis and PUD. For their pioneering and persevering efforts against considerable scorn and adversity by the medical community, Marshall and Warren were awarded the Nobel Peace Prize in Physiology and Medicine in 2005.

Epidemiology and Diseases

H. pylori has coexisted with humans for many of thousands of years and human infection is common. The Centers of Disease Control and Prevention estimates that approximately two-thirds of the world's population is infected with *H. pylori* with rates approaching 90% in underdeveloped countries. Fortunately, though infection or colonization rates are high, the incidence of symptomatic disease is low. In the U.S., 5 million people annually are diagnosed with PUD with the incidence of gastritis considerably higher. Over 40,000 individuals undergo ulcer-related surgery. Each year, more than 15,000 people die of ulcer- and gastritis-related complications, the most extreme of which is internal bleeding due to stomach or duodenal perforation. The mode of transmission of *H. pylori* is poorly understood but it is thought to be by the fecal-oral route and/or by direct mouth-to-mouth contact.

H. pylori does not cause symptomatic infection in most individuals who harbor the organism. However, colonization with the organism is a major risk factor for the development of gastritis, PUD, and is responsible for the majority of ulcers occurring in the stomach and duodenum. Also, *H. pylori* is a major cause of stomach cancer (gastric adenocarcinoma is the second leading cause of death worldwide) and is associated with an increased risk of gastric mucosa-associated lymphoid tissue (also known as MALT) lymphoma.

Pathogenesis

H. pylori is a gram-negative, spiral-shaped bacterium that grows in the mucus layer that coats the inside lining of the human stomach. To survive the harsh, acidic environment of the stomach, *H. pylori* produces an enzyme, called urease, which converts urea to ammonia. The production of ammonia neutralizes the acidic pH in the stomach and allows the organism to grow and produce disease in a

localized area, producing irritation (gastritis) and possibly a more serious ulcerative lesion. The production of the urease enzyme serves as the basis of one of the useful diagnostic tests that will be discussed in the next section.

Diagnostic Tests

Tests for the diagnosis of *H. pylori* infection are classified as invasive and non-invasive. Invasive tests are performed by endoscopy in which a tissue biopsy specimen is collected and examined histologically for the presence of the organism in tissue and by performing the CLO test which screens for the presence of the enzyme, urease, which is an indicator for the presence of *H. pylori*. Endoscopy is often performed to rule out malignancies or other non-infectious causes of the patient's symptoms. Non-invasive tests are performed when the patient has typical symptoms of *H. pylori* infection and have the advantages of being low-risk to the patient and comparatively inexpensive.

Non-invasive tests include the UBT, SAT and serologic tests that were mentioned previously. The UBT is based upon the production of the urease enzyme produced by *H. pylori*. The test is performed by having the patient ingest a preparation containing a nonradioactive, carbon¹³ isotope of urea. If *H. pylori* is present in the patient's stomach, the urea is degraded to ammonia and nonradioactive C¹³O₂. The C¹³O₂ is exhaled through normal respiration and collected in a bag and sent to a laboratory for analysis. The reported sensitivity and specificity of the UBT to detect *H. pylori* infection exceeds 93%. The UBT also can be used to evaluate patients for TOC following therapy. The SAT is an enzyme immunoassay that detects *H. pylori* antigen in a stool specimen that is shed from the patient's stomach. The SAT has a sensitivity and specificity comparable to the UBT, and can be used as a TOC, but has the added advantage that the test is approved for use in pediatric patients. Serologic tests and their disadvantages have been discussed previously which is why they are no longer recommended by the AGA and ACG for patient testing. Instead, current guidelines recommend the use of the SAT or UBT because of their superior performances.

Treatment

Since most cases of gastritis and PUD are the result of a bacterial infection caused by *H. pylori*, combination antibiotic therapy along with a stomach acid suppressor will usually result in resolution of symptoms and a therapeutic cure. Several therapeutic options are available once the diagnosis of *H. pylori* infection has been established. Following therapy, AGA and ACG recommend a TOC followup, preferably by using the SAT or the UBT.

Summary

The medical and scientific communities are indebted to Drs. Warren and Marshall for their pioneering and landmark discovery that disproved a time-honored dogma that had prevailed in medicine for decades. One of our next challenges is to abandon the use of unreliable serologic tests for the diagnosis of *H. pylori* infection and in evaluating patients for TOC. To this end, effective June 6, 2016, Laboratory Alliance will discontinue serologic testing for *H. pylori*. This change is intended to encourage the use of the more reliable tests, such as SAT or UBT, as recommended by ACG and AGA.



LA Newsmakers

Employee Anniversaries

April, 5 Years
Valerie Rouse

April, 10 Years
Robert Fiesinger

April, 15 Years
Marguerite Grosick

May, 15 Years
Rebecca Northrup

June, 5 Years
Stephen Champlin
Lucy McNamara
Keith Rando
Suzanne Swierczek

June, 10 Years
Beth Gilbert
Kimberly Johnson
Kathleen Males
Andrew Paton
Dana Simpson

New Employees

Please welcome our new employees

At our Operations Center

Michael Badner — Medical Laboratory Technician
Anthony Blaney, Jr. — Courier
Candace Buchanan — Technical Processing Assistant
Morgan Butler — Medical Laboratory Technician
James DiNicola — Transportation Dispatcher
Matthew Kinsley — Laboratory Office Assistant
Lindsay Petty — Phlebotomist
Stephen Roberts — Courier
Samantha Salisbury — Phlebotomist
Melissa Unz — Device Trial Specialist

At our Rapid Response Laboratory at Crouse Hospital

Erin Girard — Administrative Secretary

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

Cassandra Bulla — Laboratory Office Assistant
Teresa de Veyra — Medical Technologist
Danielle Goodrich — Medical Technologist

In The News

Scholarship Named for O'Learys to Benefit Clinical Laboratory Sciences Program

Upstate Medical University recently announced that the **Colleen E. O'Leary, MD, and Michael R. O'Leary, MD**, Endowed Scholarship for Clinical Laboratory Sciences (CLS) has been created to help Upstate Medical University's College of Health Professions continue to attract the finest candidates for its Clinical Laboratory Sciences program. The scholarship will also help to alleviate a critical national shortage of clinical laboratory professionals. Upstate's CLS program celebrated its 50th anniversary in 2015 and averages 18 graduates each year. The scholarship was established by the Upstate Foundation, Upstate's Department of Anesthesiology and the Upstate administration upon the recent retirement of Dr. Colleen E. O'Leary.

Michael O'Leary, MD, retired as CEO and medical director of Laboratory Alliance of Central New York. At Upstate, he holds a voluntary faculty appointment as clinical associate professor with the Department of Pathology. The O'Learys are alumni of Upstate's College of Medicine, Class of 1978. Dr. Michael O'Leary completed a residency in pathology at Upstate in 1982.

Thanks, Laboratory Alliance

Laboratory Alliance employees collected \$300 in donations for **Hospice of CNY** through contributions made on Jean Day. Jean Day was one of the company-wide activities celebrated during Medical Laboratory Professionals Week in April.

Wanda Salem Named Manager of RRL



Wanda Salem of Liverpool, N.Y., has been promoted to laboratory manager of Laboratory Alliance's Rapid Response Laboratory (RRL) at St. Joseph's Hospital Health Center. She most recently served as technical supervisor of chemistry at that laboratory.

Salem has worked at Laboratory Alliance since 2011. Prior to that she was employed as a medical technologist in various capacities at another local laboratory and physicians' offices. Also, she was an

adult education and substitute teacher in the Liverpool Central School District for more than three years.

Salem earned her Bachelor of Science in Medical Technology from the State University of New York Health Science Center at Syracuse and her Bachelor of Science in Biology from the University of Puerto Rico.

She is licensed as a clinical medical technologist in the state of New York.



American Red Cross

Save the Date Thursday, Aug. 11

Red Cross Blood Drive at Laboratory Alliance's Corporate Offices
1304 Buckley Rd. Sign up with Marsha: marshaherbst@lacny.com

Community Connections

Calendar of Events

Thursday, May 19

Hospice of CNY "Celebrating Life Through Chocolate," Bella Domani, Taft Road, North Syracuse. *Laboratory Alliance is a participant.*

Friday, June 3

St. Joseph's Hospital Health Center Gala, Turning Stone Resort Casino. *Laboratory Alliance is a sponsor.*

Monday, June 6

Foundation for Upstate Towsley Pro-Am, Kaluhyat at Turning Stone Resort Casino. *Laboratory Alliance is a participant and sponsor.*

Saturday, June 11

Green Lakes Triathlon to benefit the YMCA's programs for cancer survivors. *Laboratory Alliance donates the pace car, driven by Courier Mike Manfredi.*

Monday, July 18

Crouse Health Foundation Classic Golf Tournament, Bellevue Country Club. *Laboratory Alliance is a participant and sponsor.*



E. Carlyle Smith Memorial Open

Friday, June 17, 2016

In memory of long-time Hospice of CNY friend and supporter E. Carlyle Smith

The Links at Erie Village
East Syracuse, NY
Tee Time: 1:00pm

\$250/per golfer
Sponsorship Opportunities are available

"Captain & Crew" style tournament includes:
18 holes of golf, catered lunch, contests, raffles, snacks,
beverages, great food and
awards presentation

To reserve your spot or to sponsor the event, please call
315-634-1100, e-mail lsimpson@hospicecny.org or visit
www.hospicecny.org/golf-2016

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- Directions, maps and contact information at laboratoryalliance.com

LABlines

Comments, suggestions or inquiries should be directed to
Joan Rusin, Senior Executive Assistant,
315-461-3038, or by email to joanrusin@lacny.com