An Organization Is Only As Good As Its People

By Vickie Campany, Director of Quality Assurance

I am sure you have heard the saying, “a computer is only as good as the people who programmed it.” The same can be said for any business or organization.

In February, Laboratory Alliance found out exactly how good it is, or rather how good its employees are. On Tuesday, Feb. 12, three surveyors from The Joint Commission (formerly known as JCAHO) arrived to perform our bi-annual survey. They remained with us for four days. This was the fifth Joint Commission survey that Laboratory Alliance has undergone since it was founded in 1998.

The Joint Commission is the nation’s predominant standards-setting and accrediting body in healthcare. In addition, Joint Commission accreditation and certification is recognized worldwide as a symbol of quality that reflects an organization’s commitment to meeting performance standards and measures.

Collectively, the three surveyors possessed over 35 years experience as Joint Commission surveyors. The Joint Commission survey is designed to help an organization continuously provide safe, high-quality care, treatment and services by identifying opportunities for improvement in its processes.

Laboratory Alliance consists of four testing sites (one Operations Center and three Rapid Response Laboratories). Since it had been two years since our last survey, the surveyors had to review 24 months worth of records from all four sites.

As in previous surveys, the tracer methodology was utilized. The tracer methodology is the cornerstone of The Joint Commission onsite survey. It uses actual patients as the framework for assessing standards compliance. The “patient” is followed from the time they enter the laboratory system to the time the clinician receives the laboratory result.

Surveyors often asked to speak to staff members who were involved in the tracer patient’s laboratory testing. Employees did not mind this necessary interruption as it gave them an opportunity to share their technical knowledge.

Over the span of the four days, hundreds of records were reviewed and hundreds of questions were answered. As expected, we were very pleased with the results of the survey.

The results of the 2008 Joint Commission Survey are truly reflective of Laboratory Alliance’s Mission.

Outstanding Results on Recent Joint Commission Inspection

I would like to thank everyone at Laboratory Alliance for a very successful Joint Commission survey last month.

I am pleased to report that after four surveyors spent four days at our laboratories and our three owner hospitals, we received only three Requirements for Improvement (RFIs). The average number of RFIs received by laboratories nationwide during the last 12 months was six.

Our outstanding performance is a testament to your hard work, diligence and professionalism. All of us should be very proud of the results of this accreditation survey, as it is an affirmation of our mission and dedication to excellence. Congratulations!

Michael R. O’Leary, M.D.
Chief Executive Officer

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E-mail Encryption and HIPAA Security

By Dave Mineo, Senior Information Systems Analyst, and George Popp, Vice President of Information Systems

For years, Laboratory Alliance has secured e-mails containing Personal Health Information (PHI) using manual, time-consuming methods.

In our efforts to improve security, meet and exceed HIPAA guidelines and protect sensitive business information, Laboratory Alliance has purchased a software product called Post X by IronPort, which will be used to encrypt “external” e-mails originating from the Laboratory Alliance network.

Any e-mails created within the Laboratory Alliance network that contains PHI can be manually encrypted with the click of a button, but will automatically be encrypted by Post X based on proven rules that identify PHI. Our anticipated live date is in April.

On our customers end, the first time they receive an encrypted e-mail, they will also receive instructions to assign themselves a password to be used for subsequent e-mails. Replies to Laboratory Alliance e-mails from our customers will also be encrypted, ensuring compliance and protecting confidential information.

Internal e-mails sent within the Laboratory Alliance network are secure and do not need Post X encryption. Internal e-mails include e-mails sent from any of these locations: Operations Center, Corporate Offices and the Rapid Response Laboratories at Crouse Hospital, Community General Hospital and St. Joseph’s Hospital Health Center.

One Dose Does Not Fit All: Plavix Resistance

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

Antiplatelet therapy has become a cornerstone for both cardiovascular and neurovascular medicine. This trend has led to the emergence of the new clinical entity of Plavix resistance. Research has revealed that 5% to 30% of patients do not respond adequately to standard doses of Plavix, yet patients on chronic therapy all receive the same 75 mg/day dose. The consequences of Plavix resistance can be catastrophic, necessitating a means for monitoring antiplatelet therapy.

Laboratory Alliance now offers an FDA-approved test for assessing P2Y12-mediated platelet function, called “Plavix Response.” The Plavix Response assay measures platelet inhibition by substances known to specifically block the P2Y12 receptor.

These compounds include the thienopyridine class of drugs, including clopidogrel (Plavix) and ticlopidine (Ticlid). Platelet P2Y12 inhibition can be determined while the patient is still taking Plavix, eliminating risks associated with drug withdrawal.

The Plavix Response test joins the existing Aspirin Resistance assay, performed on the same system. For patients taking both aspirin and Plavix, the two tests may be ordered simultaneously. This assay does not replace the PFA-100 Platelet Function Screen, designed to assess overall platelet function.

For patients on chronic antiplatelet therapy, optimal levels of platelet inhibition are 40-60%. The Plavix Response assay may be useful for detecting Plavix resistance, monitoring dosage effect and ensuring compliance.

Patients with adequate platelet inhibition have an increased risk of bleeding, and withdrawal of Plavix is recommended five days prior to surgery.

Use of the Plavix Response assay may detect those patients with inadequate platelet inhibition (20%) who can be taken to surgery without delay. For those patients requiring urgent/emergent surgery, the Plavix Response assay may help optimize blood product utilization.

For more information, please consult our website www.laboratoryalliance.com or contact Hematology Manager Anne Chamberlain at (315) 410-7048.
Marilyn LeClair Named to Laboratory Advisory Council

Marilyn LeClair, Vice President of Operations, was recently named to the Laboratory Advisory Council of The Joint Commission.

The Joint Commission evaluates and accredits nearly 16,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission serves as the country's standards-setting and accrediting body in healthcare. The Joint Commission relies on a variety of advisory groups in its continuous effort to improve the safety and quality of care provided to the public. These groups provide feedback to assist it in developing and revising standards, policies and procedures that support performance improvement in health care organizations.

The Laboratory Advisory Council provides advice on such topics as improving the value of laboratory accreditation; recommending product enhancements and standards or survey process changes; and determining the impact of environmental influences.

Marilyn has been with Laboratory Alliance since its inception in 1998, serving as the Director of Hospital Operations from 2002-2004, a Rapid Response Laboratory Manager from 1999-2002, and a Technical Supervisor from 1998-1999. From 1977-1997, Marilyn worked for Community General Hospital as a Medical Technologist and a Special Assistant for Community General Hospital as a Medical Technology and is certified by the American Society of Clinical Pathologists as a Medical Technologist and a Specialist in Hematology.

In 2005, Marilyn completed an Executive Management Training Program at the Mendoza College of Business at the University of Notre Dame. She is an active member of the Clinical Laboratory Management Association Central New York chapter, currently serving as Chair of the Membership committee. Marilyn resides in Camillus, N.Y, with her husband Ron.

“Your expertise and competency in the field make you an excellent addition to our Council.”
Margaret Peck, MS, MT (ASCP)
Executive Director
Laboratory Accreditation Program
The Joint Commission

Hypervirulent Clostridium difficile
By Paul A. Granato, Ph.D., Director of Microbiology

Clostridium difficile is the leading cause of hospital-associated diarrhea in the United States. The pathogenicity of C. difficile is associated with the organism’s ability to produce a cytotoxin, called toxin A, and an enterotoxin, called toxin B.

In recent years, several studies have reported that the rate and severity of C. difficile associated diarrheal disease is increasing. In part, this increase is thought to be due to the emergence of a more virulent strain of C. difficile that is capable of producing increased amount of toxins A and B.

Toxin A and toxin B production in C. difficile is regulated by a series of genes, called an operon or, more specifically, the Pathogenicity Locus (PaLoc). Within the PaLoc is a repressor gene which is responsible for “shutting down” or repressing the production of toxins A and B.

A mutant strain of C. difficile has emerged with an 18 base pair deletion in this repressor gene which prevents the organisms from shutting down the production of toxins A and B. The presence of this mutation results in the hypersecretion of toxins up to 25 to 30 times the normal amount. This hyperproduction of toxins in this mutant strain is thought to account for more serious disease with higher mortality rates (N.E.J.M. 2005 vol. 53., 2433).

About two months ago, a patient was admitted to an area hospital who died of C. difficile pseudomembranous colitis. Because the patient experienced such a rapid decline, her stool sample was submitted to the New York State Department of Health to determine if her disease might be due to this mutant strain. Using molecular methods, the NYSDOH confirmed that the C. difficile isolate responsible for this patient’s death produced both toxin A and B and also had the 18 base pair deletion in the repressor gene, called the TcdC gene.

This patient represents the first documented case of infection due to this more virulent strain of C. difficile in Central New York. Although treatment of C. difficile infection remains the same, physicians and other health care providers should be alert to the possible existence of this hypervirulent strain of C. difficile in our community.
Many of the changes in the laboratory today represent transitions from manual to automated methodologies. Autoantibody testing is a prime example of this progression. When laboratory detection of autoantibodies became commonly used as a diagnostic adjunct for systemic lupus erythematosus (SLE) and other autoimmune disorders in the mid-70’s, the testing was performed primarily by immunofluorescent antibody (IFA) techniques. Later, enzyme-linked immunosorbent assays (ELISA) were introduced as semi-automated screening tests. Currently, automated enzyme immunoassay (EIA) methods are becoming available on chemistry platforms from several manufacturers. Development of multiplex bead immunoassay (e.g. BioRad BioPlex 2200, Wampole AtheNA, Luminex) has further expanded the potential for automation by allowing multiple analytes to be detected simultaneously in a single sample/reagent mixture. A recent prospective, multi-center study found excellent concordance between multiplex immunoassay on the BioPlex 2200 and EIA, concluding that the BioPlex 2200 is a reliable method for detecting specific autoantibodies.

When BioRad Laboratories (Hercules, Calif.) released the BioPlex 2200 in 2006, they called it “the first fully automated, random access multiplex testing platform.” The BioPlex 2200 uses proprietary magnetic beads coated with unique ligands and infused with varying ratios of fluorescent dyes.

The immunoassay principle on which the method is based is the same as many other commonly used methods and instruments, but the detection system is a sophisticated blend of flow cytometry and fluorescence detection that allows the instrument to determine not only whether antigen-antibody binding has occurred, but also the color of the bead to which the complex was bound.

This cutting-edge technology provides for a very sensitive, specific and reproducible assay. Laboratory Alliance has been reliably utilizing the BioPlex 2200 for EBV evaluation and anti-dsDNA antibody testing since October 2007.

Beginning March 3, Laboratory Alliance has expanded the use of this platform to include the ANA screen and individual assays for 10 additional extractable nuclear antigen markers (ENAs) (Table 1). Previously, ENA testing was performed at an outside reference laboratory. In-house testing should improve turn-around time and result in more concise and informative reports (Table 2).

Laboratory Alliance has been using an EIA microtiter plate screening assay for ANA testing since 1999. Currently, Laboratory Alliance has been reliably utilizing the BioPlex 2200 for EBV evaluation and anti-dsDNA antibody testing since October 2007.

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<table>
<thead>
<tr>
<th>Table 1. Extractable Nuclear Antigen Markers</th>
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<tbody>
<tr>
<td>Anti-DNA (DS)</td>
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<tr>
<td>SSA IgG Ab</td>
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<tr>
<td>SSB IgG Ab</td>
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<tr>
<td>Smith IgG Ab</td>
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<tr>
<td>SmRNP IgG Ab</td>
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<td>RNP IgG Ab (Ribonucleic Protein IgG Ab)</td>
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<tr>
<td>Chromatin IgG Ab</td>
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<tr>
<td>Scleroderma IgG Ab</td>
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<tr>
<td>Centromere B IgG Ab</td>
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<tr>
<td>Ribosomal P IgG Ab</td>
</tr>
<tr>
<td>Jo-1 IgG Ab</td>
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<thead>
<tr>
<th>Table 2. Process Improvements to Be Gained from the Transition to Fully-Automated ANA Testing:</th>
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<tbody>
<tr>
<td>1. Decreased turn-around time</td>
</tr>
<tr>
<td>o Currently, screens are performed on Monday, Thursday and Friday, with reflexively ordered titers performed on Tuesday and Friday.</td>
</tr>
<tr>
<td>o Using the BioPlex 2200 for automated ANA testing, screens will be performed daily (Monday through Friday), with results of reflex testing reported on the same day.</td>
</tr>
<tr>
<td>2. Improved report format</td>
</tr>
<tr>
<td>o Results of tests referred to outside laboratories for analysis are printed in a separate section of the patient’s report. Currently, results of ENA tests, such as SSA/SSB or Jo-1, are not reported in the same section of the report as the ANA screens or anti-dsDNA antibody results.</td>
</tr>
<tr>
<td>o Using the BioPlex 2200 for automated ANA testing, results of related tests will be printed sequentially on the report.</td>
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</table>
Laboratory Alliance Offers Serum Ethylene Glycol and Methanol Testing

By Roy Huchzermeier, Ph.D., Chemistry Research and Development Consultant

Ethylene glycol is a colorless sweet-tasting liquid that is a component of many household products including anti-freeze, de-icing solutions and some brake fluids. Owing to its accessibility and sweet taste, ethylene glycol is frequently implicated in accidental and intentional poisonings. Methanol, also known as methyl alcohol or wood alcohol, is a highly toxic compound that is present in many common household products such as automobile windshield washer solvent, gas line antifreeze, paint strippers and fuel for small stoves. Although methanol poisoning is less common than ethylene glycol poisoning, its accessibility and toxicity make it an important agent to consider in suspected toxic ingestions. In cases of suspected ingestion of either ethylene glycol or methanol, it is important to establish serum concentrations of these compounds as rapidly as possible in order to guide and monitor treatment.

Laboratory Alliance recently obtained approval from the New York State Department of Health to test for ethylene glycol and methanol concentrations in patient sera. This testing is performed at the Operations Center in Liverpool on a new analytical platform, gas chromatography. The availability of local testing provides a significant service to our community. Local poison control specialists and regional hospitals should enjoy much faster turnaround times than was previously available.

This is expected to greatly enhance the level of treatment available in suspected poisonings. Previously, the nearest laboratories capable of performing this testing were Strong Memorial Hospital in Rochester and Albany Medical Center. Samples from Syracuse area hospitals had to be transported by local law enforcement agencies to one of these hospital laboratories.

Ethylene glycol and methanol testing are currently available to Laboratory Alliance’s three owner hospitals and will soon be available to the SUNY Upstate Medical Center and other regional hospitals.

The ordering of serum ethylene glycol and/or methanol testing is handled differently than other tests. As has always been the protocol, all requests for testing must first be approved by the Upstate Poison Control Center. Once the order has been approved, samples will then be transported to the Operations Center laboratory by Laboratory Alliance couriers. Results will be reported directly to the Poison Control Center specialists, as well as to the hospital where the patient is located. Serum ethylene glycol and/or methanol testing is available 24/7.

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Featured Department

There is never a dull moment in Central Receiving at our Operations Center. The employees process over 150,000 patient requisitions per month. In addition to this front end processing, the Central Receiving Department prepares patient reports for distribution. The department is responsible for problem resolution involving billing, specimen type and test order discrepancies. The staff processes incoming samples in a timely and efficient manner to expedite testing within the clinical departments. Our next issue will feature our Central Receiving staff at our Rapid Response Laboratories.

Central Receiving at the Operations Center includes:
Group photo, left to right: Sara Waldron, Lisa Horning, Jeremy Fuller, Stephanie Sokolowski, Jose Feliciano, Laura Buehler, Donald Stone, Jacqueline Zimpfer, Brian Meaker, Antonietta Lane, T onya Woodard, Laura Murray, Chrissy Traphagen, Deb Cullen, Supervisor Carrie Nappa, Katie Brooks, Kathryn Sigona, Kimberly Hayes and Jessilee Jones. Individual photos: Director of Support Services Jeff Coyne, Ashton Keith, Brittany Barrella, Diane Kampf, Sara Clarke and Night Supervisor Ron Sweet. Missing from the department photo are: Mary Kate Clancy and Leslye Ebert.

Laboratory Alliance was a corporate sponsor of the 39th Annual Heart Ball to benefit the American Heart Association held on Feb. 2 at the Oncenter. Representing Laboratory Alliance were, left to right, in the front row: Dr. Jayne Healey, Dr. Michael R. O’Leary, Patricia Kearns (widow of Frank Kearns), Cheryl Lovelace (daughter of Pat Kearns and the late Frank Kearns); and in the back row: Dr. Patrick Healey, Anne Marie Mullin, Dr. Colleen O’Leary, Barbara Guiffrida, Karen Carter and John Carter.

Patient Service Center News

Relocation
Community General Hospital PSC
Physicians Office Building South
4900 Broad Road, Syracuse, NY 13215
On Monday, June 2, our PSC currently in Suite 1D, will be open for business in Suite 1K, just down the hall. This suite will afford us a larger waiting room and more space for phlebotomy.

Closing - Lease Expired
Cazenovia
4 Chenango Street
This Patient Service Center will close permanently at 4:30 p.m. on Friday, April 25.

Our lease has ended and the physician practice located in the building is in need of more space. The practice will expand into the space we currently occupy. We ask our Cazenovia customers to visit another of our many convenient locations, such as Northeast Medical Center in Fayetteville and Medical Center East in East Syracuse. We appreciate your business and thank you for understanding.

Congratulations
To Katie Brooks, Laboratory Office Assistant at our Operations Center, who will graduate from LeMoyne College on May 18 with a Bachelor of Arts in psychology, with a concentration in early childhood education/special education.

Congratulations to the “Lab Crew,” Dr. Rachel Elder’s women’s soccer team from Sports Center 481, on winning the league’s women’s division on Feb. 24.

Dr. Elder is the Director of Laboratories at Crouse Hospital. Laboratory Alliance sponsored the team’s T-shirts.
Employee Anniversaries

March
5 Years
- Carol Freitas
- George Kiteveles
- Malinda Kuney

10 Years
- Luanne DeFelice
- Barbara Gonnela
- Eric Henry
- Kathleen Laubenstein
- Mary Meaker
- Michele Scott
- Karen Strouse
- Lawrence Vanderhoff

April
10 Years
- Patricia Alvaro
- Deborah Cullen
- Lorna Dewitt
- Olga Farrell
- Susan Hayes
- Claire Huchzermeier
- Margaret Paton
- Martha Stewart

Community Outreach
Representatives from Laboratory Alliance continue to promote all laboratory professions and spread awareness about clinical laboratory science.
We recently participated in the following career fairs:
- Nottingham High School – March 7
- Solvay High School – March 7
- Liverpool High School – March 14
Future school career fairs include:
- Beard Middle School – April 3
- Henniger High School – April 3
- Camillus Middle School – April 4

New Employees
Please welcome our new employees:

At our Corporate Office
- **Terri April**, Controller
- **Kathleen Hass**, Quality Assurance Specialist
- **Melanie Coons**, Information Systems Analyst

At our Operations Center
- **Stephen Arnold**, Technical Admin. Assistant
- **David Weaver**, Courier
- **Jose Feliciano**, Laboratory Office Assistant
- **Heidi Welch**, Technical Processing Assistant
- **Robert Smith**, Laboratory Office Assistant
- **Michele Leppard**, Laboratory Office Assistant

At our Rapid Response Laboratory at Community General Hospital
- **Jeffrey Baker**, Technical Processing Assistant
- **Savannah Montulli**, Technical Processing Assistant

At our Rapid Response Laboratory at St. Joseph’s Hospital Health Center
- **Ruslan Ali-Zade**, Laboratory Office Assistant
- **Juan Salazar**, Laboratory Office Assistant

At our Rapid Response Laboratory at Crouse Hospital
- **Dora (Tish) Elliott**, Shift Supervisor

Recent Activities

**Tuesday, Feb. 5**
*Syracuse Auto Dealers Association* (SADA) Charity Preview to benefit 13 area not-for-profits. Laboratory Alliance was a corporate sponsor and pictured below are employees who attended on behalf of Laboratory Alliance.

**Thursday, March 6**
Greater Syracuse Chamber of Commerce Annual Meeting. Laboratory Alliance was a corporate sponsor.

**Friday, March 14**
*CNY Clinical Laboratory Management Association Quarterly Meeting*. Gina Potenza, Director of Information Systems, was a speaker at the event.

**Thursday, March 20**
*Syracuse Chamber Business Show*, Cargill Exhibit Center, New York State Fairgrounds, 9 a.m.-6 p.m. Laboratory Alliance was one of the many exhibitors.

*Representing Laboratory Alliance at the Syracuse Auto Dealers Association Charity Preview were, left to right, Vickie Campany, Rose Martin, Karen Carter, Nancy Sniffen, Laboratory Alliance friend Doug Nelson, Malinda Kuney, Jeff Peterson, Ann Marie Derecola and Jeff Coyne.*
Enjoy Men Who Cook on April 25
Laboratory Alliance is, once again, a proud sponsor of the 20th annual Men Who Cook fundraiser to benefit The Mental Health Association of Onondaga County, being held on Friday, April 25, at the Hotel Syracuse. Advanced tickets are $45 each or $160 for a packet of four (until April 18). Tickets at the door are $50 each.

For more information or to purchase tickets, visit www.menwhocookmha.org or call (315) 422-9400.

Sample an international smorgasbord of appetizers, entrees and desserts prepared and served by 100 local businessmen, professionals, elected officials and celebrities.

• Try to guess the Best Dish and Best Table winners
• Bid on Silent Auction items and services donated by local companies.
• Enjoy live music while you eat.

This year’s Honorary Chair is Nicholas J. Pirro, right, pictured here at last year’s event with another ‘chef.’

New ANA Testing Algorithm
Continued from page 4
samples with “Positive” or “Borderline” screening results are further tested by IFA and reported as an ANA titer with pattern.

Under the new testing algorithm, ANA screens will be reported as either “Positive” or “Negative.” Those samples testing “Positive” will automatically reflex to further testing for all 11 ENA markers listed in Table 1.

To facilitate clinicians’ transitioning to the new algorithm, we will continue to perform IFA testing on positive ANA screens until May 5.

For more information regarding this new test service, please contact Cheryl Haskins, Chemistry Manager, at (315) 410-7014.

Calendar of Events

Friday, April 25
Men Who Cook to benefit the Mental Health Association of Onondaga County, Hotel Syracuse, 5:30-8:30 p.m. Laboratory Alliance is a corporate sponsor.

Saturday, April 26
Heart Health Awareness Program at the Skaneateles Community Center, 9 a.m.-4 p.m.

Sunday, May 18
Golissano Children’s Hospital Miracle Ride
Laboratory Alliance is a corporate sponsor.

Friday, May 30
St. Joseph’s Hospital Health Center Foundation Gala
Laboratory Alliance is a corporate sponsor.

Laboratory Alliance offers the SurePath® Pap test.

✓ Increases the detection of abnormal/precancerous cells
✓ Reduces unsatisfactory results
✓ Provides greater clarity for diagnosis
✓ Lowers the incidence of inconvenient repeat testing
✓ Screens for HPV infection on the same specimen if requested

“For all these reasons, I asked my doctor to send my Pap test to Laboratory Alliance. Ask your doctor about this type of screening for the early detection of cervical cancer.”

To learn more, visit us at www.laboratoryalliance.com

LABlines is a bi-monthly publication by LABORATORY ALLIANCE of CNY. Comments, suggestions or inquiries should be directed to Anne Marie Mullin, Vice President of Business Development and Marketing, at (315) 461-3036, or by e-mail to annemariemullin@lacny.com.