Drugs of Abuse Testing: An Overview

By Michael R. O’Leary, M.D., CEO

Substance abuse is a significant problem in the United States. More than 1.7 million emergency department visits in 2006 were associated with drug abuse or misuse, of which 55% involved an illicit drug. In addition, pain and addiction-management physicians are treating more patients who require prescriptions for addictive and narcotic drugs. For this reason, drug of abuse urine (DAU) testing is frequently requested by clinicians in a variety of settings to diagnose overdose, verify compliance and exclude illicit or unknown prescription drug use.

The common drugs or classes available for DAU testing include amphetamines, barbiturates, benzodiazepines, cocaine metabolites, methadone, opiates, PCP and tricyclic antidepressants (TCA). More recent additions to this extensive menu include MDMA (Ecstasy) and oxycodone.

Immunoassays are frequently used in clinical laboratories to perform DAU testing since they are easily automated and provide rapid turnaround times. Depending on the assay, an antibody is designed to detect a specific class of drugs (for example barbiturates), a parent drug (methadone) or a metabolite (benzoylecgonine, a metabolite of cocaine). However, the high sensitivity of immunoassays does result in some cross-reactivity, with occasional false-positive results. For example, false-positive opiate screens can occur in patients taking quinolone antibiotics or in those with recent poppy seed ingestion.

Of the various biological specimens available for testing, (urine, blood, hair, saliva, nails and others) urine is preferred due to the ease of collection and high concentration of drugs and their metabolites. Most drugs are rapidly cleaned from the circulation, resulting in low serum levels. The higher concentration of drugs/metabolites in the urine increases the chance of detection and provides for longer detection times (i.e. hours, days etc.).

Qualitative results, positive or negative for a drug, are actually semi-quantitative in that positive results reflect a drug concentration that is greater than a specific cut-off level. Cut-off levels are established through a combination of regulatory mandates (Substance Abuse and Mental Health Services Administration), analytical considerations and historical convention. It’s important to remember that negative results reflect either NO drug present or a concentration that is below the cut-off.

To effectively manage patients with suspected substance use or abuse, clinicians should appreciate the limitations of DAU testing, including interfering substances. Urine samples adulteration is a serious problem in urine drug testing. Sample adulteration is achieved by substitution (another person’s urine), dilution (overhydration) or the addition of chemical adulterants (bleach, acid etc.). The use of adulterants may cause false-negative results by either interfering with the screening test and/or destroying the drugs present in the urine. Most laboratories offer tests to detect sample adulteration on request.

It is important for clinicians to recognize the preliminary nature of immunoassay based DAU tests. All immunoassay positive results must be confirmed by gas chromatograph-mass spectrometry (GC-MS) testing. GC-MS is the most accurate and reliable method for detecting small quantities of specific drugs. Since GC-MS is both costly and time-consuming, it is typically reserved for confirmatory testing of screen-positive samples.

It is important for all healthcare professionals to understand that DAU testing, while useful, has drawbacks. It does not provide information such as time since last ingestion, duration of abuse or state of intoxication. Results from DAU testing must be assessed in conjunction with clinical history and physical examination in order to avoid significant consequences associated with misinterpretation. Please refer to an article in the Fall 2008 issue of LabLines for additional information.
Blue Iris eLaborate Software Upgrade Planned
By George Popp, V.P. of Information Systems

Many of our customers use Blue Iris software to retrieve their laboratory test results. Mitem Corporation has announced that they will make software upgrades by the end of this year to Blue Iris eLaborate.

The upgrades include a number of new features and product enhancements. It will require that its users can support the new version with their third party software, such as Internet Explorer and Microsoft Windows.

Please note that the following will be required to run this product upgrade:

1. Blue Iris will no longer support the use of Internet Explorer Version 6. Future versions of the Blue Iris software may not function correctly on Version 6. Supported Internet Explorer versions will include Internet Explorer Version 7 or 8, and any subsequent versions that Microsoft releases.
2. Users must run Windows XP or a later operating system to make use of Internet Explorer 7 or higher.
3. Blue Iris will support Firefox and Safari browsers on both Windows and Apple computers.

We are excited about the new capabilities this upgrade will offer and are here to assist you in making this transition.

For assistance, contact our Customer Service Department at (315) 461-3008 and ask for Information Systems.

Laboratory Alliance Recognized for Contributions to Local Economy

CenterState CEO recognized 172 companies in October as the 2010 Economic Champions. As a group, these companies created 1,644 new jobs; invested $400,765,000 in equipment and capital improvements; and added 732,015 square-feet of space at their locations over the last year.

Laboratory Alliance of CNY was one of the honorees recognized for contributions to the economic growth of the CenterState New York region through their capital expenditures, hiring of new employees, expansion or relocation due to growth, and for state or national recognition.

“Many of these honorees often fly under the radar, yet, their collective impact on the regional economy is enormous,” said David Duerr, president of the CenterState Chamber of Commerce. “All of these Economic Champions can be justifiably proud of their everyday contributions to the growth of the CenterState New York economy.”

The celebration took place during the 8th Annual Economic Champions Luncheon at the Holiday Inn Syracuse-Liverpool with nearly 400 CenterState CEO members, community leaders, and guests in attendance.

Accepting on behalf of Laboratory Alliance were, left to right, Vickie Campany, Nancy Sniffen, Barbara Guiffrida, George Popp and Marilyn LeClair.
The measurement of methylmalonic acid (MMA) in serum, plasma or urine is performed to monitor intracellular vitamin status. Vitamin B₁₂ is an essential co-factor in the enzymatic conversion of MMA into succinic acid, and therefore a deficiency of vitamin B₁₂ results in elevated levels of MMA.

Since the 1960s, many methods, utilizing a host of different technologies, have been developed to measure serum or urinary MMA. The most accurate and specific of these are based on mass spectrometry coupled with either gas chromatography (GC-MS) or high performance liquid chromatography (LC-MS). LC-MS procedures often involve simpler and less time-consuming sample preparation procedures than corresponding GC-MS procedures. Therefore, we set out to develop and validate an LC-MS method for MMA.

After searching the scientific literature for published LC-MS methods for MMA we settled on a method developed by a team of clinical laboratory scientists in Sweden. We purchased the HPLC column for this method from a Swedish company.

Our international collaboration started right away as we communicated regularly with a member of that company's technical support team, Patrik, who also happened to be one of the authors of the published procedure that we wanted to implement. We had many communications with Patrik by phone and e-mail as we implemented his methodology on our instrument system. Patrik was instrumental in assisting us in the development of a prototype assay.

Our initial feasibility studies indicated that the LC-MS method for MMA was capable of acceptable precision and accuracy, but as we performed this procedure on an increasing number of serum samples, similar to running the procedure in a production mode, we observed deterioration in the performance of the method. At this point we searched for a clinical laboratory that had put this LC-MS into clinical practice, and would likely have encountered the same problem with which we were wrestling.

Since this LC-MS method is relatively new, we were unable to find another clinical laboratory in the United States that was using it. We had to expand our search outside the U.S. This led us to a Norwegian clinical laboratory.

We contacted Dr. Albena Mihailova of Akershus University Hospital in Oslo, Norway. We were very pleased that Dr. Mihailova was willing to share her knowledge and experience with us. Dr. Mihailova’s department, Medical Biochemistry, performs routine MMA testing by LC-MS.

She suggested a particular column washing procedure. Her advice allowed us to regenerate our column and restore the overall performance of the MMA method. Dr. Mihailova went out of her way to provide us with other valuable insight and information regarding the new LC-MS method as well.

Many thanks go out to Dr. Mihailova and Patrik for helping us with our development and implementation of the best LC-MS method for MMA. After we complete final validation studies and obtain New York State Department of Health approval, we will offer MMA by LC-MS test to our clients.

Dr. Albena Mihailova of Akershus University Hospital in Oslo, Norway, shared with us her knowledge and experience with the LC-MS procedures for measuring MMA. Dr. Mihailova’s Medical Biochemistry Department, performs routine MMA testing by LC-MS. After we complete final validation studies and obtain New York State Department of Health approval, we will offer the MMA by LC-MS test to our clients.
All of the current Local Coverage Determinations (LCD’s) and National Coverage Determinations (NCD’s) are now available, for your convenience, on the Laboratory Alliance website under “Health Care Providers.” The LCD and NCD information on our website is updated quarterly.

Marilyn LeClair Named CNY CLMA Laboratorian of the Year

By Anne Chamberlain, Manager of Hematology and Board Member of the CNY CLMA Chapter

The Clinical Laboratory Management Association (CLMA) of Central New York Chapter announced the Laboratorian of the Year at their annual meeting in October 2010. The Laboratorian of the Year award is given to an individual who demonstrates at least two of the following attributes: leadership, quality performance and/or community involvement. Marilyn LeClair, (shown left) Vice President of Operations at Laboratory Alliance, was honored with this prestigious award.

Marilyn has been in a leadership role for the majority of her laboratory career; as an assistant supervisor, a supervisor, a laboratory manager, a director of operations and as the vice president of operations.

Her excellent technical knowledge and management skills have been instrumental in her career advancement at Laboratory Alliance. Marilyn has always set high standards for herself as well as for those who report to her, always seeking to achieve a higher goal.

Marilyn is patient and readily provides support and guidance to who all her report or work with her, no matter how busy or involved in a project she may be. She interacts competently and professionally with personnel at all levels including hospital administrators, pathologists and top level sales representatives.

She is the champion of a LEAN project that was initiated this past April at our Operation Center. She constantly provides encouragement, leadership and guidance for that process improvement initiative.

Marilyn is an active member of the local CLMA Chapter. As the Membership Committee Chair she actively works to recruit and retain members for the CNY chapter. Additionally, she serves at the national level as a member of The Joint Commission’s Laboratory Advisory Council. Past contributions to the laboratory profession include serving on the board of directors for our local CLMA chapter and as a phlebotomy instructor at Onondaga Community College.

Marilyn is very involved in her church community where she is a cantor and music director at St. Ann’s Church. She frequently lends her outstanding musical talent to various religious celebrations, community theater and choral presentations. Her musical talents have been enjoyed by those attending select Syracuse Symphony Orchestra concerts.

She is the consummate professional and serves as a mentor to those who work with her.

Visit us online at www.laboratoryalliance.com
Managing Diabetes Begins with Learning the Facts
By Anne Marie Mullin, V.P., Business Development & Marketing

Diabetes has reached epidemic proportions in the U.S. The Centers for Disease Control and Prevention (CDC) estimate that more than a quarter of all Americans aged 20 years or older have diabetes symptoms.

Understanding diabetes is the first step to managing it. With so much information available, it’s easy to stay informed on the causes of diabetes, risk factors, warning signs and prevention tips.

Diabetes is the most common disorder of the endocrine (hormone) system. It occurs when blood sugar levels in the body consistently stay above normal. Diabetes occurs when the body cannot regulate blood sugars. It is a disease brought on by either the body’s inability to make insulin (type 1 diabetes) or by the body not responding to the effects of insulin (type 2 diabetes). Insulin is one of the main hormones that regulates blood sugar levels and allows the body to use sugar (called glucose) for energy.

Diabetes often goes undiagnosed because many of its symptoms seem so harmless. The early detection of diabetes symptoms and treatment can decrease the chance of developing the complications of diabetes.

Type 1 Diabetes can include the following symptoms: frequent urination, unusual thirst, extreme hunger, unusual weight loss, extreme fatigue and irritability.

Often, people with Type 2 Diabetes have no symptoms, but they may experience the following: any of the type 1 symptoms, frequent infections, blurred vision, cuts/bruises that are slow to heal, tingling/numbness in the hands/feet and recurring skin, gum or bladder infections.

While diabetes and pre-diabetes occur in people of all ages and races, some groups have a higher risk for developing the disease than others. Diabetes is more common in African Americans, Latinos, Native Americans, and Asian Americans/Pacific Islanders, as well as the aged population. This means they are also at increased risk for developing pre-diabetes.

Pre-Diabetes, also called impaired glucose tolerance, occurs when blood sugar levels that are higher than normal but not high enough to be classified as diabetes. While people with pre-diabetes usually have no symptoms, it’s almost always present before a person develops type 2 diabetes. Complications normally associated with diabetes, such as heart disease, can begin to develop even when a person has only pre-diabetes.

The recommended test for diagnosing diabetes and pre-diabetes is the hemoglobin A1C test. A1C is a marker of chronic hyperglycemia, reflecting average blood glucose levels over a two to three month period of time.

While not everyone with type 2 diabetes is overweight, obesity and lack of physical activity are two of the most common causes of this form of diabetes. Obesity and lack of physical activity are responsible for nearly 95% of diabetes cases in the United States, according to the CDC. A family history and age increases the risk for type 2 diabetes.

Type 1 diabetes can’t be prevented, but type 2 diabetes has modifiable risk factors which can help you manage your blood glucose levels. The best way to prevent or delay the onset of type 2 diabetes is through a healthy lifestyle. Change your diet, increase your level of physical activity and maintain a healthy weight.

Progression to diabetes among those with pre-diabetes is not inevitable. Studies have shown that people with pre-diabetes who lose weight and increase their physical activity can prevent or delay diabetes and return their blood glucose levels to normal.

To learn more, ask your doctor for information or visit the following websites: Centers for Disease Control and Prevention: Diabetes Public Health Resource at www.cdc.gov/diabetes or the American Diabetes Association at www.diabetes.org.

Welcome to our New Clients

DeRoberts Plastic Surgery
Syracuse, N.Y.

Dr. Kenneth Gale
Syracuse, N.Y.

LeMoyne College
Student Health Center
Syracuse, N.Y.

Women’s Health
Camillus, N.Y.

You’re Invited

Employees and a Guest
Join us for the Laboratory Alliance Holiday Party
Saturday, January 8
Holiday Inn Electronics Parkway
6 p.m.-midnight
Peers Select Beth Blair to Receive Corporate CHAMP Award

Beth Blair’s co-workers boast that Beth has all of the attributes of a CHAMP and is one of Laboratory Alliance’s most positive employees. It was a pleasure for Dr. O’Leary to present Beth with the CHAMP Award at the annual company clambake in September, recognizing her consistent demonstration of Caring, Helpfulness, Accuracy, Motivation and Professionalism.

“Beth is always calm in stressful situations and she has a calming effect on her co-workers,” said one peer.

Beth is a Senior Medical Technologist who works in both the Chemistry and Research and Development Departments at the Operations Center. Recently, she was selected to be the LEAD on the Lean Project at the Operations Center.

“Beth is always willing to take on new responsibilities,” said one co-worker, while others noted, “Beth is well liked and has a terrific sense of humor.” “If she has a problem, she will always find the solution.”

Beth joined Laboratory Alliance in 2007 after graduating from SUC at Fredonia with a Bachelor of Science in Medical Technology and from SUNY Morrisville with an Associate of Applied Science in Medical Technology. She was employed as a hospital laboratory medical technologist and as a technical coordinator at Centrex Clinical Laboratories before joining Laboratory Alliance.

We are proud to recognize Beth as our September CHAMP.

Recognizing Outstanding Customer Service

Sara McCabe, Referral Testing Department, has demonstrated excellence in customer service through her interactions with the coordinator of Laboratory Client Services at the Cleveland Clinic. Here she is pictured, center, with her supervisor Deb Cullen, Manager of Referral Testing, and CEO Dr. Michael R. O’Leary.

Recently, Sara was complimented for her knowledge, professionalism and helpfulness. She presented some suggestions that resulted in a positive interaction for a patient of the Cleveland Clinic.

This is not the first time that Sara has been the recipient of complimentary remarks. Laboratory Alliance is proud of her job performance and recognizes her contribution to service excellence.

IN THE NEWS

A recent issue of the Clinical Microbiology Newsletter (Vol. 32, Issue 19, 2010) includes an article co-authored by Laboratory Alliance’s Russell Rawling, M.S. M(ASCP) SM, RM (NRM) SM, Marcia Degilio MT(ASCP)SM, Katrina M. Zeglin MT(ASCP) and Paul A. Granato, Ph.D., Microbiology Department at Laboratory Alliance and at SUNY Upstate Medical University; Hospital Epidemiologist, Community General Hospital; Clinical Professor, Department of Medicine, SUNY Upstate Medical University. They co-authored with four others, a Case Report titled “Tuberculous Cervical Lymphadenitis.” For a copy of the report and discussion relating to the topic, contact Dr. Granato by e-mail at paulgranatophd@lacny.com.

New Employees

Please welcome our new employees

At our Operations Center
Ann Adams – Courier
Trisha Bennett – Phlebotomist
Eric Cross – Phlebotomist
Jerry Gavenda – Courier

Shannon McManus – Technical Processing Assistant
Gigi Sgroi – Laboratory Office Assistant
Jenna Van Der Vogen – Histotechnician

At our Rapid Response Laboratory at St. Joseph’s Hospital
Sonya Sekovski – Laboratory Office Assistant
Beth Dhayer – Laboratory Office Assistant

At our Corporate Office
Lynda Brittell – Customer Service Representative
Eric Hayden – Information Systems Analyst
Matthew Messenger – Information Systems Analyst

Employee Anniversaries

October, 5 years:
Marsha Herbst
Dan Ho
Linda Montgomery
Emma Harris
David LaTour

October, 10 years:
Robert Cavelli
Adam Nappa
Neil Wescott

November, 5 years:

December, 5 years:
Sebby Abbate
Linda Ball
Linda Hart

Another look at the Corporate Challenge

As we reported in our summer issue of LabLines, we had a wonderful turnout of runners and walkers representing Laboratory Alliance at the Chase Corporate Challenge, held June 22 at Onondaga Lake Park. There were so many people that we inadvertently omitted the picture on the left, above! Our apologies. Below, the entire group taking cover from the rain.
Saturday, Oct. 23  Community General Hospital Foundation’s ‘Fall Harvest Gala,’ Hotel Syracuse, Laboratory Alliance was a sponsor.

Thursday, Oct. 28- Friday, Oct. 29  Clinical Laboratory Management Association and American Association for Clinical Chemistry Annual Conference and Exhibition, ‘High Stakes Healthcare,’ Turning Stone Casino, Verona, N.Y., Laboratory Alliance was a major sponsor and exhibitor.

Friday, Dec. 10  Blood Banks Association of New York State Seminar, Laboratory Alliance Corporate Office. Laboratory Alliance is a sponsor.

Saturday, Jan. 8  Laboratory Alliance Employee Holiday Party, Holiday Inn, Liverpool, N.Y.

**C A L E N D A R   O F   E V E N T S**

If you live in Central New York, it’s likely you are vitamin D deficient. **Do you know your vitamin D level?**

**Why worry about vitamin D?**
When we don’t replace vitamin D daily, our body will meet its needs by stealing calcium from our bones, weakening them over time — a process that can contribute to the development of osteoporosis and weaken our immunities. Vitamin D deficiency may also increase the risk of heart disease and colon and prostate cancer.

**Testing provides important information.**
A vitamin D deficiency is diagnosed by measuring the concentration of a specific form of vitamin D in blood. Unfortunately, many tests do not measure the supplemental form of vitamin D. It is imperative to request a total vitamin D test (25-OH vitamin D) in order to assess your true status — a total test that measures vitamin D2 and D3 levels in the blood.

Ask your doctor if you should be tested. To learn more, visit our website at www.laboratoryalliance.com or call (315) 461-3008.

**Celebrating at the Annual Clambake**
Laboratory Alliance employees, families and friends enjoyed a beautiful day and great food at our company clambake held Saturday, Sept. 11, in North Syracuse.

Some diners took breaks in the pavillion, while others enjoyed games and activities.

Maura Conan, right, with about 15 hoops around her, won the hula hoop contest. She is the daughter of Tim Conan, our corporate attorney from Costello, Cooney and Fearon.

**LABlines**

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Comments, suggestions or inquiries should be directed to Anne Marie Mullin, Vice President of Business Development and Marketing, (315) 461-3036, or by e-mail to annemariemullin@lacny.com.