USDTL News

October 2011 | The Leader in Newborn Toxicology | Volume 2 Issue 4

Buprenorphine in Pregnancy

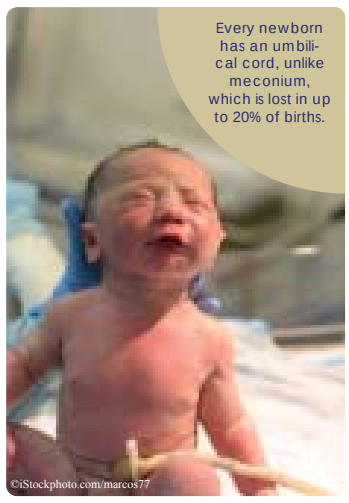
by Douglas Lewis
President and Scientific Director

Buprenorphine is a semi-synthetic opioid that is used to treat opioid addiction in higher dosages (>2 mg) and to control moderate acute pain in non-opioid tolerant individuals in lower dosages (about 200 µg). In pregnant women treated for opioid addiction, buprenorphine has been found to be superior to methadone in reducing withdrawal symptoms in the newborns, according to a recent study funded by the National Institute on Drug Abuse (NIDA).Methadone is currently the recommended treatment for opioid-addicted pregnant women, and when properly used is considered relatively safe for the fetus. However, it is associated with neonatal abstinence syndrome (NAS) — a cluster of symptoms stemming from opioid withdrawal in the newborn—often requiring medical treatment and extended hospital stays. Buprenorphine is a more recently approved medication for treating opioid addiction, but less is known about its effects in pregnant women and their babies. This study found that, compared to methadone, buprenorphine resulted in similar maternal and fetal outcomes, yet had lower severity of NAS symptoms, thus requiring less medication (morphine - 1.1 versus 10.4 milligrams) and less time in the hospital for their babies (10 versus 17.5 days).

Buprenorphine, however, has recently been reported to be widely available "on the street" and is being diverted to illicit use. This raises the question of identifying newborns that exhibit NAS symptoms but test negative for commonly abused opioid drugs. New tests that identify buprenorphine in meconium and umbilical cord can provide neonatal clinicians with valuable information concerning their babies exhibiting symptoms of NAS.

USDTL unveils alcohol biomarker in umbilical cord

by Bob Demaree
Clinical Projects Manager



After increasing demand for an alcohol biomarker in umbilical cord samples, USDTL released the CordStat® EtOH assay, screening for the direct alcohol biomarker phosphatidylethanol (PEth), in October. PEth is an abnormal phospholipid formed in cell tissues following alcohol ingestion.

Collecting umbilical cord offers several advantages over meconium collection, the main one being availability. Meconium is lost *in utero* in about 20 percent of live births. In other instances, a diaper is misplaced during the collection process, and healthcare practitioners no longer have the entire sample to screen. Umbilical cord offers a universal sample for testing and requires much less time to collect, resulting in a faster turnaround time for testing.

PEth in blood exists as a component of the red cell membrane, whereas in the umbilical cord tissue, PEth is a component of the various cord cells' membranes. PEth is a mid-term biomarker measurable after exposure of approximately six to 12 drinks in one week, usually after a binge episode. Sample amount is approximately 6 inches of umbilical cord.

CordStat® EtOH is an ideal clinical assay for healthcare practitioners concerned with monitoring newborns at high risk for having been exposed to alcohol during pregnancy and for developing Fetal Alcohol Spectrum Disorders. The assay can be ordered as an add-on test to one of our standard CordStat® 5-, 7-, 9-, 12- and 13-drug panels. To order CordStat® EtOH, researchers and clinicians can contact Client Services at (800) 235-2367 or at customer.service@usdtl.com.

Is CordStat FDA Approved?

by Douglas Lewis
President and Scientific Director

One of the most frequently asked questions we hear from clients, healthcare professionals and lawyers is whether CordStat® is FDA approved. The simple answer is "no" and the reason is that CordStat® is a "Laboratory Developed Test (LDT)." LDTs are regulated under the Clinical Laboratory Improvement Amendment of 1988 (CLIA88), not by the FDA. CLIA88 allows clinical laboratories to develop and validate their own diagnostic tests for a variety of conditions.

Clinical laboratories are permitted do this provided that the tests are validated and a part of the laboratory's CLIA license. These in-house tests are commonly referred to in the industry as "homebrews," or, more recently, "Laboratory Developed Tests (LDTs)." CLIA labs are inspected either by personnel from CMS or by third party inspectors such as the College of American Pathologists (CAP). In several states, including New York, additional state regulations apply. In USDTL's case, we are inspected and accredited by both CAP in Forensic Drug Testing and by the State of New York as a Forensic Laboratory.

Some of the confusion about the need for FDA approval is the FDA issuing draft guidance documents concerning In Vitro Diagnostic Multivariate Index Assays (INDMIA).

An IVDMIA is a device that:

1. Combines the values of multiple variables using an interpretation function to yield a single, patient-specific result (e.g., a "classification," "score," "index," etc.), that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, and
2. Provides a result whose derivation is non-transparent and cannot be independently derived or verified by the end user.

These types of tests usually have a lab derived software function that provides a result that healthcare professionals could not derive for themselves and could not interpret the results. CordStat® is a tissue drug analysis procedure that is no different than the thousands of forensic tissue drug analyses performed by medical examiners and coroners in post-mortem investigations. Such results are routinely received by pathologists and are interpreted based on the scientific literature available to all medical personnel. The results are not derived or non-transparent. Thus, CordStat® is regulated entirely under CLIA88 and not by the FDA.

Ask the president

President Douglas Lewis

Q: How long do I have to dispute a result?

A: USDTL saves negative specimens for seven days after initial accessioning. Seven days is longer than the customary three days that most labs retain negatives. This duration should allow clients a reasonable time to decide if dispute resolution is needed, to contact customer service and initiate the process. Positive specimens are stored frozen for one year following accessioning.

Our Client Services Representatives will provide you with the necessary paperwork for you to sign and return to initiate the re-test process. Once the paperwork is in order, Client Services will return a re-test result to you in one to two working days. If you have any questions after receiving the results, please contact Client Services and they will either assist you or direct you to one of our forensic toxicologists to discuss the case with you.

Got a question for USDTL? Ask President and Scientific Director Douglas Lewis. E-mail heather.sliwinski@usdtl.com with your questions, and you may be featured in our newsletter!

USDTL Upcoming Events

October 11-12: FANNP's 22nd National Neonatal Nurse Practicioner Symposium Clinical Update and Review
Clearwater Beach, Florida

October 13-14: Professional Outreach Education Conference"Promoting Excellence in Perinatal & Neonatal Care"
Spokane Valley, Washington

November 3: Riverside Methodist Hospital Perinatal Conference
Lewis Center, Ohio

November 9-10: The Fetus & Newborn: State-of-the Art-Care
Las Vegas, Nevada

November 13-15: Developmental Interventions in Neonatal Care
Las Vegas, Nevada

December 4-6: Hot Topics in Neonatology
Washington, DC

USDTL™
advancing the gold standard

1700 S. Mount Prospect Rd. | Des Plaines, IL 60018 | (800) 235-2367 | www.usdtl.com