




MEDTOX Hospital Lab Quarterly Review

We are pleased to present the quarterly newsletter focusing on the latest services and technologies for hospital laboratory testing. Our goal at MEDTOX has always been to provide our clients with the highest level of service in the industry and the Quarterly Review is another way to keep you informed and up-to-date on what is new at MEDTOX and in the industry.

BUPRENORPHINE

 The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System now offers a 13 Panel (Part# 604022) in addition to our 12 Panel that includes screening for buprenorphine.

Buprenorphine is a semi-synthetic opioid analgesic structurally similar to morphine but with a longer duration of action. The FDA has recently approved the use of buprenorphine formulations (Subutex[®], Suboxone[®]) for the treatment of opiate dependence in the United States. These compounds are the first drugs available for treatment of opiate dependence that can be prescribed in the physician's office. This change is expected to provide patients greater access to needed treatment.

Subutex[®] and Suboxone[®] treat opiate addiction by preventing symptoms of withdrawal from heroin and other opiates. Buprenorphine is a long-acting drug which allows for less frequent dosing than other treatment paradigms. It is intended as an alternative to methadone treatment, and like methadone, can result in dependence and abuse. Buprenorphine is a Schedule III drug and its use in treatment for narcotic addiction is closely monitored.

At MEDTOX, we've seen a sharp increase in drug screens that include buprenorphine. In one key drug testing population, the buprenorphine positive rate in 2009 was twice the rate of methadone positives and approximately half the rate of opiate positives.

A sample screening non-negative for buprenorphine on the PROFILE®-V MEDTOXScan® Drugs of Abuse Test System, may be sent into MEDTOX Laboratories, Inc. for a LC/MS/MS confirmatory analysis.

Clinical Toxicology Testing

MEDTOX offers extensive clinical laboratory testing for Reference Labs, Hospitals, Specialty Clinics and Coroners. We began as a toxicology lab more than 25 years ago and today are a full-service provider and one of the industry's leading reference laboratories, fully certified by CLIA, CAP and state proficiency programs. We provide a full menu of clinical laboratory tests, plus live support from technical experts and personalized service from a dedicated account team. For you, that means accurate results at the right price and fast answers to complex questions whenever you need them.

Every customer program also includes a personalized IT experience. MEDTOX supports traditional LIS and EMR integrations, proprietary systems that support standard protocols, and customized interfaces. We also offer a Web-based electronic ordering system called AutoWeb™ — a secure, reliable tool that gives your staff fast remote access to lab data online. Use it to place orders and eliminate paperwork, retrieve results, generate reports, or track the status of an individual patient's test. There is no direct interface. All you need is a Web browser.

Visit <http://www.medtox.com/TestCatalog.aspx> for a comprehensive test menu available at MEDTOX or contact your MEDTOX hospital representative today for more details.

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Urine Screens on Mothers and New Borns: Recently we have spoken to a number of hospitals that are using the MEDTOX Profile II ER or MEDTOXScan PV system to screen moms and at risk new born urine samples. It is important to remember that these screens, like any other immunoassay screen, are not definitive...the result is a 'presumptive positive' and should **not** be considered a 'final confirmed result'. Repeating the test a second or third time is not a 'confirmation', nor is screening it on a different manufacturer's screening test. Confirmation testing by a more definitive method—such as GC/MS or LC/MS/MS is strongly advised before making decisions for child protection agencies to act on 'results'. It is important that lab, nursing, physicians and other staff understand the difference between 'screens' and 'confirmations' and act appropriately with these 'results'.

Immunoassays use an antibody to screen for one or more drugs, and do so based on their chemical shape/structure---similar to a key (drug) fitting **into** a lock (antibody). If the key fits into the lock, the immunoassay screen is 'presumptive positive'. The definitive confirmation test ultimately checks to see if the key will open the lock. A number of keys can fit into the lock, *but not open it* (i.e. screen positive, but confirm negative). The antibody is basically 'looking for a shape' that fits the lock. If the unknown drug 'fits' the lock, even somewhat close, the screen can be 'presumptive positive'. The confirmatory method (like GC/MS) deals with the drug on a molecular level---there are many highly specific chemical parameters like GC retention time, ion fragments, ion fragment ratios, etc. that **MUST** be met in order to identify, quantitate, and report a drug as confirmed. This is in addition to the actual data package meeting all standard, quality control, etc. parameters set for in the validated forensic method SOP.

We have seen cases where the mom has received ephedrine during the course of labor. Ephedrine is structurally very similar to methamphetamine, and can and does 'cross react' with the methamphetamine antibody. The presence of a sufficient amount of ephedrine in the urine can result in a presumptive positive screen for methamphetamine, but not amphetamine. Depending on when the urines are collected in relation to the ephedrine dose, mom and/or newborn may screen positive for methamphetamine. Acting on these screening results can have serious consequences for the baby, the parents and the hospital. It is extremely important to send the presumptive positive urine(s) off to a reference laboratory for confirmation testing for amphetamine and methamphetamine by GC/MS or LC/MS/MS and act only on 'confirmed results'. This testing is **definitive** since it looks at the 'chemical fingerprint' of the drug on a molecular level. GC/MS or LC/MS/MS results are the 'gold standard' and are forensically defensible in court. In the case that 'ephedrine' is the cause of the presumptive positive methamphetamine screen, the confirmation test by GC/MS would be **NEGATIVE** for the following: amphetamine, methamphetamine, MDMA and MDA. Note, it is not necessary to identify the presence of ephedrine, you want to 'rule in' or 'rule out' the presence of the 'amphetamines'. MEDTOX Laboratories has a full range of GC/MS and LC/MS/MS confirmation tests available, and is capable of preparing litigation packages and offering expert testimony if necessary.

Since collecting urine from a newborn can be challenging, and since the volume of urine obtained can be low, an alternate specimen is meconium. The volume of meconium is larger, and also offers an advantage of looking for drugs over a wider period of time than urine. Urine samples can basically record drug use/exposure over the last day or last few days. Meconium can record the drug usage of the mom during the last trimester timeline. A single meconium sample can encompass several weeks to a month of drug use history. Several meconium samples can encompass even a

larger time period.

Note: The baby's urine screen results may not match that of meconium based on the fact that the time period sampled may not coincide with that of the urine. Meconium testing (screening and GC/MS confirmation) is offered by MEDTOX Laboratories.

Note: Both urine and meconium confirmation testing is performed to the limits of quantitation (LOQ) and reported as such.

Confirmations of Positive Screens on MEDTOX Rapids: A final note: Work place confirmation cut offs should not be used for urine confirmations, since you are interested in detecting the 'presence' of the drug, and not using an 'administrative' cut off to determine if the drug is there. You may ask, 'what is the difference?' Here is an example—a cocaine metabolite quantitative result of 148 ng/mL would be considered 'administratively negative' based on the current administrative work place cut off of 150 ng/ml. (This will change in the near future). It is not a matter that drug isn't there (it is!), or that the drug can't be reliably confirmed (it was!), but rather an arbitrary cut off used in workplace testing. The physician should be aware of the fact that clinically 'drug is present' and base decisions on that. Another example—breath alcohol testing---just because someone has a blood alcohol of '0.079' (administrative cut off = 0.080) doesn't mean they weren't drinking alcohol—they just happen to be 'below the legal limit'---alcohol is present. Clinical decisions should be based on the absence or presence of drug---the physician would want to be aware of a '0.079' ethanol concentration even though it is not considered 'legally drunk'.

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Feedback



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