



Letter from the President: celebrating 20 years of innovation



I find it hard to believe that 20 years have passed since my wife, Veronica Lewis, and I started USDTL. We founded the lab on the principles of bringing two technologies to the reference laboratory market that only research or Olympic doping laboratories had done. Our intent was to perform forensic meconium drug analyses, all GC/MS confirmations and perform anabolic steroid testing on urine specimens. In 1991, these tests were new territory for reference laboratories.

We succeeded in developing the MecStat® testing procedure for meconium, which has grown to become the standard for newborn drug exposure testing. Over the years, the MecStat® panels have grown from an initial 5-drug panel to 12-drug panels with several add-on drugs. In 1998, USDTL introduced the first test for fetal alcohol exposure, MecStat® EtOH. MecStat® EtOH tests for fatty acid ethyl esters in meconium that correlates with alcohol exposure.

Anabolic steroids proved to be a technical success. The testing was challenging and demanding, but highly satisfying for the analysts. Fate intervened in 1994. USDTL put in a bid for pre-employment hair drug testing for a newly built casino. Our GC/MS resources only allowed us capacity to do either anabolic steroids or hair testing, and hair testing won out. We embarked on a journey to become a superior hair-testing lab and continue to today.

In 1996, a child abuse investigator asked if children's hair could test positive for drugs in their environment. A recent paper had just showed that children living with cocaine users had as much cocaine in their hair as the adult users. Therefore, we put hair testing to new use. The ChildGuardSM test has identified thousands of exposed children that other tests may not have identified.

USDTL initiated another credit to its success with our first NIH Small Business Innovative Research (SBIR) Grant, developing MecStat® EtOH. Since 1997, USDTL has received seven more grants with funding exceeding \$2.5 million. Some of the tests created by these grants include CordStat® umbilical cord drug test, PethStat® blood test for the alcohol biomarker phosphatidylethanol, and HairStat® EtG and NailStatSM EtG tests for the alcohol biomarker ethyl glucuronide.

The past 20 years have been a spectacular journey for USDTL and its team members. We founded USDTL on the idea of performing tests that were not originally available to the medical and forensic communities. We have continued our mission and promise to keep developing better ways of diagnosing drug and alcohol use.

Thank you for your continued support of USDTL. We appreciate being a part of your organizations for the past 20 years and look forward to more years to come.

Douglas Lewis
President and Scientific Director

Meconium unavailable as much as 27 percent of time

by Joseph Jones
Vice President Laboratory Operations

A 2010 review of literature by USDTL showed the rate of noncompliant meconium specimens experienced by researchers ranged from 9.8 percent to 27.8 percent. Although meconium is arguably the most popular form of newborn drug and alcohol testing, USDTL rejects a significant amount of meconium specimens as Quantity Not Sufficient (QNS).

Meconium does offer many advantages over other potential specimen types to detect exposure to drugs and alcohol during pregnancy. Maternal hair, nails and urine require maternal consent, which is difficult to get willingly from a drug user. Collecting enough meconium for testing is more likely than collecting enough newborn hair, nails or urine. Lastly, meconium has a large window of detection, showing maternal drug history up to 20 weeks back in the pregnancy.

Even with these advantages, meconium causes problems for collectors. Routinely, specimens are not available for testing. Physicians sometimes place test orders after the meconium has passed when they notice signs of withdrawal. In up to 20 percent of live births, the new-

born has already passed meconium in utero, or the babies at highest-risk provide the smallest quantities of specimen for testing.

Most commercial laboratories request similar amounts of meconium for testing purposes. Laboratories need enough specimen for an initial test and a confirmation of presumptive positive initial tests. Our laboratory requests a minimum of 2.0 g (one heaping teaspoon). Each test at USDTL requires 0.5 g for an initial test and at least two confirmation tests. Ideally, enough specimen remains on file for referee testing.

Between July and September of 2010, USDTL received 4181 meconium specimens and rejected 256 (6.1 percent) of those as QNS.

USDTL has conducted two studies that involved the use of meconium to detect prenatal drug and/or alcohol exposure. The studies¹⁻² yielded noncompliance rates of 22.4 percent and 23.2 percent. USDTL did not document the reasons other than QNS for noncompliance at the time.

Therefore, USDTL conducted the 2010 review to determine the extent of noncompliance experienced by other meconium researchers. USDTL identified seven large studies from

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Table 1. Percentage of meconium specimens missed in newborn toxicology studies

Reference	Participants Enrolled (n)	Meconiums (n)		
		Available	Unavailable	Missed (%)
1	345	265	80	23.2
2	588	456	132	22.4
3	218	157	61	27.9
4	75	58	17	22.7
5	11811	8527	3284	27.8
6	546	436	110	20.1
7	51	46	5	9.8
8	215	168	47	21.9
9	102	88	14	13.7

Umbilical cord chain of custody protects hospitals, staff

by Douglas Lewis
President and Scientific Director

Creating a "chain of custody" of umbilical cord specimens in hospitals helps to protect the institution in case of a legal challenge. Chain of custody may prevent every member of the hospital team that touched the specimen from having to testify.

Clients often question the purpose of the chain of custody form. Chain of custody in legal circles refers to the "movement and location of evidence from the time it was obtained until the evidence is presented in court" (Mr. Heim's Chat, 2007). This may seem irrelevant in a clinical setting, but courts can challenge any CordStat® case with legal consequences.

The chain of custody is a paper trail of collection. The form includes custody, control, transfer and analysis of the specimen. Chain of custody (a.k.a. chain of evidence) proves that the evidence given in court concerning the newborn is the same evidence collected at birth. The form also proves that no one tampered with the evidence. The court can exclude the evidence if hospitals do not maintain chain of custody, which may go against the child's best interests.

The practice of keeping chain of custody is simple, but does require diligence every time hospital staff transfers the specimen. At the

birthing site, a simple paper record of who collected the specimen and to whom it was transferred is sufficient. Continue this process until the staff member assigned to sending the specimen out via courier seals the shipping package.

Once shipped, the chain of custody is re-established when the laboratory receives and opens the specimen. At this point, USDTL initiates an internal chain of custody record and documents the specimen's handling through final analysis.

Maintaining detailed chain of custody is a simple way to protect both the institution and the baby. Keep in mind, chain of custody usually shows its value when you do not have accurate forms.



Courts can challenge any CordStat® case. They can exclude the test results if hospitals do not maintain accurate chain of custody.

Meconium (cont.)

Table 2. Kapi'olani Medical Center conducted a consecutive birth study involving 546 infants and the collection of their meconium specimen for testing (Derauf, 2003). Out of the 546 infants enrolled in the study, 120 (22%) were unavailable for testing.

Reason	Unavailable (n)	Unavailable (%)
Collection was missed	17	3.1
Discharged before passing	72	13.2
Provided <1.0g for analysis	21	3.8

1999 to 2010.³⁻⁹ The collection teams for these studies are motivated and well trained. Table 1 identifies the total number of participants, number of adequate specimens and number of non-compliant specimens.

The Kapi'olani Medical Center study went one step further and documented the various reasons for noncompliance.⁶ Their results are very similar to what USDTL routinely observes. Table 2 summarizes Kapi'olani noncompliance.

References

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During a routine in-service visit a few years back, one of our valuable meconium clients brought this issue to our attention, and a solution was proposed. After two NIDA-sponsored SBIR research grants, USDTL now offers Cord-Stat[®] as a reliable replacement for meconium collection. By testing umbilical cord instead of meconium, USDTL has reduced the chance of rejected or unavailable specimen interfering with newborn testing and treatment.

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Featured FAQ of the quarter

Q: Can drugs given to the mother during birth show up in newborn test results?

A: Yes, drugs administered to the mother during birth can show up in meconium, umbilical cord and breast milk depending on the timing. The opiates morphine, codeine, hydromorphone and hydrocodone, for example, can all appear in results if given to the mother. The levels present in the results cannot indicate how much of the drug was given or taken. A positive result can only confirm with the medical record that the drug was in fact given to the mother, and therefore, present in the newborn's system. Levels cannot reveal if additional doses were taken prior to birth. Also, drugs given to the newborn for treatment fully incorporate into the gut and may show up in a meconium sample, but do not affect umbilical cord or breast milk results.

-Heather Sliwinski

Marketing Communications Manager

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