USDTL News

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Defense in depth for quality assurance

by Joseph Jones
Vice President Laboratory Operations

"That's not my result."
"They mixed me up with someone else."
"I do not use *that* drug."

If you have been in the business of drug monitoring for any length of time, you have heard these and other similar statements. Although USDTL goes to great lengths to provide accurate and timely results to our clients, drug testing is a human endeavor, and mistakes will happen. However, USDTL does everything in its power to resolve these issues and, when an error occurs, ensure it will not happen again.

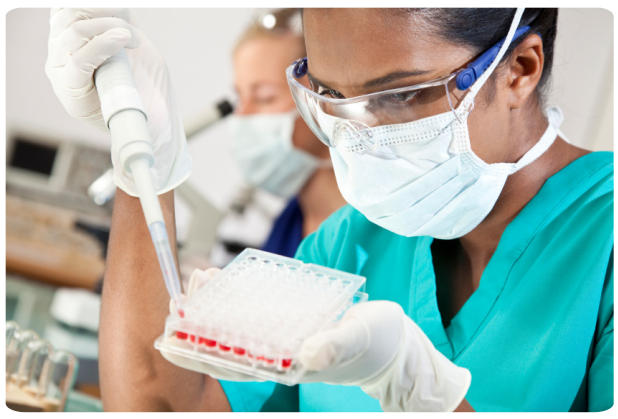
Defense in depth is a military strategy borrowed by the laboratory industry. Quite simply, this strategy takes an approach to risk that passes the specimen and results through multiple layers of testing and review. USDTL uses this strategy right from the point of specimen collection and includes the client and donor.

At the point of collection, USDTL provides clients with pre-printed barcode labeled requisition forms. An identical barcode label is peeled from the requisition form and applied to the specimen. This barcode creates the primary forensic identification of the specimen.

At the laboratory, accessioning personnel scan the barcodes of the specimen and requisition form. The Laboratory Information Management System (LIMS) forces a match prior to receipt into the laboratory. A specimen whose barcode label does not match its corresponding requisition form barcode label is rejected by the computer system.

USDTL uses multiple identifications for each specimen, such as the requisition form number, donor name, donor ID and a laboratory accession number assigned at the time of receipt. Once accessioned into the LIMS, each specimen container is verified (specimen verification) against work lists pulled from the system. Similarly, all requisition forms are reviewed (order entry verification) against work lists generated from the LIMS. These review steps are conducted after all specimens have been received for the day.

Each specimen forwarded to the initial testing section is identified by barcode label. The initial testing instruments read these barcodes, perform the tests and automatically download the results to the LIMS. The instrument operator generates batch review reports to assist with the data review process, which includes review of the chain-of-custody, calibration, positive controls, negative controls and patient results. Once accepted, a final reviewer reviews the data



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Multiple identifications for each specimen are used in the laboratory to ensure correct results for each donor.

a second time.

After acceptance of the initial testing data, the initial negative certification reviewer generates the final toxicology reports for all of the negative specimens. This individual verifies each field on the report. Lastly, a final negative certifying scientist executes the final review of the negative specimens and releases those reports to the client via fax or email.

Presumptive positive specimens are batched, re-identified, re-aliquoted, re-extracted and forwarded to the confirmation laboratory. As with the negative specimens, the review process includes an operator review, final data review, initial positive certification review and a final positive certification review.

When the client receives the final toxicology reports, it is very important to verify that all of the identification numbers and names match with the numbers and names from your copy of the multipart requisition form. If you observe any discrepancy, please do not hesitate to notify the laboratory to investigate.

Finally, the last line of defense is the donor. Even with all the safeguards and checks in the laboratory, risk cannot be completely avoided. Therefore, USDTL keeps all positive specimens for one year for the purpose of re-testing. A re-test incurs a "confirm only" fee (pre-paid by the donor) that is waived if the original result is overturned. Pre-payment of a re-test fee generally discourages insincere disputers. If you have a donor that disputes a result and is willing to pre-pay for a re-test, contact Client Services at (800) 235-2367 to receive a disputed result form. You will be assigned a primary contact for the dispute who will remain in contact with you until the issue is resolved.

If USDTL can be of any further assistance to ensure a smooth and accurate testing process, please let us know. Our clients and high-quality service are our priority.

Featured FAQ of the quarter

Q: Is umbilical cord considered maternal or fetal tissue?

A: When considering switching from meconium to umbilical cord testing for newborn drug exposure, healthcare practitioners often wonder if they will have to acquire maternal consent to collect the cord. When testing umbilical cord, you are not testing the mother. Umbilical cord tissue is formed from fetal origins during the first five weeks of gestation.[4] Therefore, since umbilical cord is not maternal tissue, the law in most states does not require maternal consent to collect it. Only a few states arbitrarily require maternal consent to collect umbilical cord. Please check with your hospital policies to ensure consent is not required.

-Heather Sliwinski
Marketing Communications Manager

Neonatal abstinence syndrome follows maternal substance use

by Robert Demaree
Clinical Projects Manager

The most recent data from the SAMHSA National Survey on Drug Use and Health found that 5.1 percent of pregnant women reported use of illicit drugs during pregnancy, and 10.6 percent of women admitted consuming alcohol. Among those using alcohol, 4.5 percent reported binge drinking, the consumption of five or more drinks on a single occasion.[1] Neonatal abstinence syndrome (NAS) symptoms occur in 55 to 94 percent of drug-exposed newborns.[2]

NAS occurs when the newborn experiences withdrawal following maternal substance use during pregnancy.

In 1986, Finnegan, et al., introduced an objective scoring tool to identify those behaviors produced by fetal exposure to illicit drugs. These signs and symptoms include central nervous system, metabolic, vasomotor, respiratory, and gastrointestinal issues[3]. In addition to the initial problems related to withdrawal, the neonate may experience intrauterine growth restriction (IUGR), premature birth, seizures and birth defects. Drug using mothers are less likely to seek healthcare during the pregnancy. IV drug users are at higher risk for exposure to AIDS and HIV.

The opioid drug group has the highest association with NAS. Other substances like amphetamines, barbiturates, cocaine, marijuana and alcohol cross the placenta and may result in withdrawal symptoms.

Newborn drug testing is a valuable tool to identify exposure. USDTL offers broad test panels in a variety of sample matrices including umbilical cord, meconium and breast milk, with a buprenorphine add-on assay to any panel.

A new alcohol biomarker assay is in development for monitoring fetal alcohol exposure. This new test method will utilize an abnormal phospholipid, phosphatidylethanol (PEth), as a direct alcohol biomarker. Introduction of this new alcohol biomarker assay is planned for mid- to late-2011. Contact Client Services at (800) 235-2367 or visit www.usdtl.com for additional information.

USDTL newborn drug panels

5-drug panel
Amphetamines
Cannabinoids
Cocaine
Opiates
PCP

7-drug panel
Methadone
Barbiturates

9-drug panel
Benzodiazepines
Propoxyphene

12-drug panel
Meperidine
Tramadol
Oxycodone

References

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[2]American Academy of Pediatrics Committee on Drugs. Neonatal Drug Withdrawal. Pediatr. June 1998;101(6):1079-88

[3]Finnegan LP. Neonatal abstinence syndrome: assessment and pharmacolotherapy. In: Neonatal therapy: an update. New York, NY Excerpta Medica; 122-46

[4]Pansky B. Dynamic Anatomy and Physiology. 1975.

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