USDTL News

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The science of nail growth offers advantages over hair

by Douglas Lewis
President and Scientific Director

Nails grow in two dimensions, in length and in thickness. Fingernails show three to six months of drug history.

The analysis of keratinic matrices such as hair and nails has been of much interest recently as a way to extend the window of detection of substances for times far longer than traditional matrices such as blood or urine provide. Nails, especially fingernails, are just now being recognized as a valid and accessible long-term repository matrix for the determination of a variety of substances.

Originally nails were used for the determination of metals such as lead, cadmium, copper, zinc, iron and magnesium as well as many others. Recently, nails have become an alternative to hair testing for drugs of abuse and alcohol consumption.

Nails have some unique characteristics that differentiate it from hair. The first major difference is that nails lack the pigmenting of melanin. This eliminates any color bias present in hair for basic drugs such as cocaine or methamphetamine.

The second major difference is that nails grow in two dimensions, growing in length from the nail matrix and in thickness as the nail moves along the nail bed. This fact means that drugs and metabolites are added to the nail plate whenever the compounds are present in blood,

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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.

The strategy takes an approach to risk that passes the specimen and results through multiple layers of testing and review.

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 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

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Defense in depth strategy

Collector applies matched barcode
↓
Accessioning – receives matched barcodes
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Specimen Verification
↓
Order Entry Verification
↓
Initial Data Review
↓
Final Data Review
↓
Initial Negative Certification
↓
Final Negative Certification
↓
Re-identification of presumptive positive
↓
Initial Data Review
↓
Final Data Review
↓
Initial Positive Certification
↓
Final Positive Certification
↓
Client Review of Final Report
↓
Donor Dispute-Retest

Featured FAQ of the quarter

Q: The donor has a valid prescription for amphetamine (Adderall®) and reports taking it everyday. Why was the HairStat® screen negative for amphetamines?

A: The immunoassay reagent used for the HairStat® amphetamines initial test is very specific for methamphetamine and MDMA (ecstasy) and is not very sensitive to amphetamine itself. However, the reagent used for the UrineStat℠ initial test is very specific for methamphetamine and amphetamine, but not very sensitive for MDMA. If amphetamine detection is essential for your particular situation, you may order a directed confirmation for amphetamine, which will ensure maximum sensitivity.

-Joseph Jones
Vice President Laboratory Operations

Zolpidem (Ambien®) offered as inexpensive add-on in urine

by Joseph Jones
Vice President Laboratory Operations

The reported emergency department visit rate due to zolpidem has increased 121 percent over the study period of 2004 through 2008, according to the Drug Abuse Warning Network (DAWN). Zolpidem, classified as a non-benzodiazepine hypnotic, has been prescribed for use as a sleep-aide as early as 1992 in parts of Europe.

Zolpidem has not been included in standard urine assays because of the lack of a suitable commercially available homogeneous immunoassay. Historically, laboratories have relied on cumbersome ELISA screening technology or direct analysis by LCMSMS, which is very costly. Our immunoassay vendor, Immunalysis, has now released a new homogeneous immunoassay for zolpidem and its metabolite, zolpidem carboxylic acid, in a simple robust format, allowing zolpidem to be an inexpensive constituent of any custom profile.

A urine specimen provides approximately two to three days of drug history. All presumptive positive specimens are confirmed by LC-MSMS.

USDTL can customize panels specific for testing needs. Zolpidem can be added to our standard base UrineStat℠ 12-drug panel. Contact Client Services at (800) 235-2367 to discuss custom profiles and pricing.

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Defense in depth (cont.)

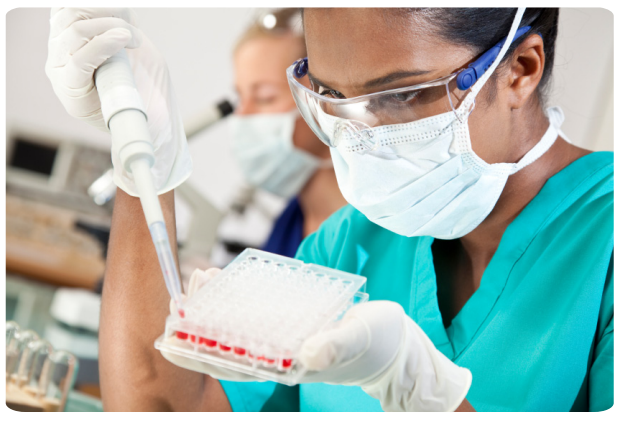
the negative specimens and releases those reports to the client via fax or email.

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.



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

Nail growth (cont.)

and the lag time from potential last exposure to time of cutting is rather short, about one to two weeks, similar to the time it takes new drug exposure to show up in hair erupting from the follicle. This fact also eliminates the mistaken notion that nail scrapings were the appropriate specimens necessary for a time-averaged drug history. Simple nail clippings provide an integrated history of drug exposure over the course of the nail growth, some three to six months.

Much of the knowledge of drug incorporation into nails resulted from research into the incorporation of antifungal drugs into the nail plate as a means to monitor effectiveness of treatment for onychomycosis. The researchers were surprised that drugs such as itraconazole appeared in nail clippings shortly after initiation of treatment, not three to six months later as the theory of the time suggested. Additional experiments showed that the protein incorporation was occurring all along the entire length of the nail bed along with the antifungal drug.

USDTL has used this information to extend its hair drug testing panels to nails, which often are available when head hair is either too short to sample or adulterated via bleaching, dyeing, perming or chemical straightening. In some instances, nails are the preferred specimen, especially when the drug or metabolite does not bind well to hair and has a rapid washout. NailStat^{SM} is offered in standard 5-, 7-, 9- and 12-drug panels. An alcohol biomarker in hair and nails is currently under development.