DTAB's Process for Evaluating the Scientific Sufficiency of the Oral Fluid Specimen for Federal Workplace Drug Testing

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Process

- Follow the HHS-recommended staggered timeline for evaluating the scientific sufficiency of alternative specimens for use in federal workplace drug testing programs
  - Begin with the evaluation of oral fluids

Step 1

- Task the Drug Testing Advisory Board with assessing the state of the science of oral fluid as an alternate specimen for drug testing within the federal workplace drug testing programs
  - January 26-27, 2011 meeting

"The scientific, legal, and public policy information for drug testing oral fluid … specimens … is not as complete as it is for the laboratory-based urine drug testing program"

Step 2

- Identify lead scientific experts to assist DWP and the DTAB is assessing the state of the science of oral fluid

Lead science experts

- Yale Caplan, Ph.D., DABFT
- Edward J. Cone, Ph.D., FTCB
- Dennis J. Crouch, M.B.A.
- J. Michael Walsh, Ph.D.

Step 3

- Review the current state of the science of oral fluid
  - January 26-27, 2011 meeting

Review

- History
- Specimen
- Drug analytes and cutoffs
- Methodologies: initial, confirmatory, validity
- FDA approval
- Proficiency testing
- Best practices experiences
- Laboratory data

Step 4

- Perform an exhaustive oral fluid literature search
  - To date, ~620 peer-reviewed references

Bibliography

- For the first time, the preamble to the proposed oral fluid Guidelines will have each answer supported by at least one literature reference

Step 5

- Draft proposed revisions to the Mandatory Guidelines to include oral fluid
  - Revise the original 2004 proposed revisions to the Mandatory Guidelines to include only oral fluid
  - Harmonize with the question/answer format of the 2008 urine Mandatory Guidelines

Step 6

- Identify topic areas in which DWP, the DTAB, and the scientific experts have reached preliminary consensus

Preliminary consensus

- Guidelines should express cutoffs on basis of “native oral fluid concentrations”
- Devices must meet FDA specifications and NLCP PT requirements
- Immunoassays should be FDA cleared and laboratory validated
- Immunoassays may or may not be linked to the device
- The initial assay is not limited to immunoassay
- The initial test, i.e., LC-MS-MS, must be validated by laboratory
- The collection device must have an accurate volume indicator
- Collection of 1 mL is adequate
- Split specimens may be collected simultaneously or serially within a defined time of each other

Step 7

- Identify the topics areas in which further research is required

Topics

- Analytes/cutoffs
- SVT/validity
- Collection
- Collection devices
- Testing

Analytes/Cutoffs

- What are the appropriate analytes and cutoffs concentrations for the initial and confirmatory tests?

SVT/Validity

- Are there appropriate markers or tests for oral fluid that would reveal adulteration, substitution, and/or dilution?

Collection

- What are the requirements for collecting an oral fluid specimen?

Collection devices

- What are the requirements for an oral fluid collection device?

Testing

- Is LC-MS-MS or other methodologies a viable alternative to immunoassay?

Working groups

- To assist DWP, the DTAB, and the science experts, other science experts were identified to serve on working groups dedicated to each of the topics areas
  - These working groups are in the process of being approved through Ethics and Office of General Council

Other topics

- Other significant scientific, legal, and public policy concerns related to the oral fluid specimen have also been identified and are being discussed with the appropriate federal officials

Step 8

- Prepare and publish a request for information
  - Identify the topic areas in which information from the public will be requested
  - May 4, 2011 meeting

Step 9

- Review the information submitted by the public
  - July 12-13, 2011 meeting

Step 10

- Deliberate on the recommendation of oral fluid as an alternate specimen for drug testing
  - September 12-13, 2011 meeting

Goal

- Based on its state of the science research and after addressing the significant scientific, legal, and public policy concerns raised by public commenters and Federal agencies, DTAB will/will not recommend proposed revisions to the Mandatory Guidelines to include oral fluid as an alternate specimen
  - If recommended, the proposed revisions will be published in the Federal Register for public comment