Drug Testing

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Workplace Drug Testing Program

- Federal Program Established in 1988
- Detection and Deterrence
- Types of Drug Tests
  - Pre-employment
  - Random
  - Post-accident
  - Reasonable Suspicion/Cause
  - Return to duty
  - Follow-up
  - Other (Voluntary)

Mandatory Guidelines for Federal Workplace Drug Testing Programs

- Specifically Applicable to Federal Agencies
  - Authority: Executive Order 12564 and Public Law 100-71
- DOT Regulated Industries
  - Authority: 49 CFR Part 40
- NRC Regulated Industries
  - Authority: 10 CFR Part 26

Historically

- Urine Specimens
- Laboratory-Based Program

Urine – Advantages

- Analytical Methodology
  - Immunoassays
  - GC/MS
- Accuracy and Precision
- Mature Program
  - Interpretation of Lab Results
  - Well-established in Legal System

Urine - Disadvantages

- Invasive
- Adulterated
- Substituted
- Leakage of Specimen During Shipment
- Degradation of Analytes

Proposed Changes to the Mandatory Guidelines

- Development Began in April 1997
  - 3-day meeting of SAMHSA's Drug Testing Advisory Board
    - Presentations on Alternative Drug Testing Matrices

Selected Alternative Matrices

- Hair
- Oral fluid
- Sweat

Potential Advantages of Alternative Matrices

- Less Invasive Collection
- Multiple Sampling May Be Possible
- Greater Specimen Stability
- Lower Disease Risk in Specimen Handling
- Easier Shipment and Storage
- Differences in Window of Detection
- May Be More Difficult to Substitute/Adulterate

Potential Disadvantages of Alternative Matrices

- Dealing with Lower Analyte Concentrations
- May Require More Sensitive Analytical Methods
  - Examples: Elisa, GC/MS/MS, MS^n
- May be Detecting Parent Drug Rather than Metabolite, or Both Parent and Metabolite
- Some specimens require “chronic use” of substance for detection at achievable cutoff concentrations

Additional Testing Options

- Point of Collection Tests (POCTs)
  - Urine
  - Oral Fluid
- Instrumented Initial Test Facility (IITF)
  - Hair
  - Oral fluid
  - Sweat
  - Urine

Common Requirements for Development

- Scientific acceptability
- Court/legal acceptability
- Community acceptability
- FDA-cleared
- Establish cutoffs
- Stringent Quality Assurance and Performance Testing
- Cost versus Benefit
- Bottom Line: Each Test Result Must be Accurate and Reliable

Testing Specimens

- Specify Analytes
- Establish Cutoffs
- Specify Specimen Validity Testing Requirements

Urine Cutoffs

- Initial Test Concentration
  - Marijuana 50 ng/mL
  - Cocaine 300
  - Opiates 2,000
  - PCP 25
  - Amphetamines 1,000

Urine Cutoffs (continued)

- Confirmatory Test Concentration
  - Marijuana 15 ng/mL
  - Cocaine 150
  - Opiates
    - Morphine 2,000
    - Codeine 2,000
    - 6-AM 10
  - PCP 25
  - Amphetamines
    - Amphetamine 500
    - Mathamp 500

Instrumented Initial Test Facility (IITF)

- Essentially, the screening part of a traditional screening and confirmatory testing laboratory

HHS Certification of Laboratories and IITFs

- Inspection Program
  - Semi-annual inspections
  - Trained inspectors
  - Number of inspectors
    - Size of Laboratory
- Performance Testing Program
  - Quarterly sets of Samples
  - Minimum criteria for acceptable performance

POCTs

- POCT Device Must Be FDA-cleared
- POC Test Must Perform Drug and Validity Tests "Like" a Laboratory
  - Same analytes and cutoffs
  - SVT and negative drug test results from POCT must be equal to results from laboratory tests
- Non-instrumented or Instrumented
- User certifies POCT
  - Tester
  - Drug and Validity Testing Devices
  - Location

Potential Advantages of IITFs and POCT

- Faster Turn-around Time for Negatives
- Faster Personnel Decisions
- Cost Efficient

Potential Disadvantages of POCT

- Tester Training
- Maintain Tester Proficiency
- Additional Chain of Custody Issues
  - Documentation/Forms
  - Testing Aliquot
  - Resealing Specimen
  - SVT and Drug Tests are Separate Devices/Procedures at This Time

Specimen Collectors

- Trained
- Document Training

Specimen Collection Sites

- Inspect

Medical Review Officer

- Trained
- Pass Examination
- Retain Certification

Future of Alternative Specimen Drug Testing

- Federal Register Notice published April 13, 2004
- 285 Public Comments
- Evaluating Public Comments
- Publish Final Guidelines (Date ?)
- Implementation Date
  - Probably 1 Year (from publication date)