

NLCP Implementation of the Revised Mandatory Guidelines 2010

Special PT Program

John M. Mitchell, PhD
Co-Director, National Laboratory
Certification Program
Center for Forensic Sciences
RTI International

2009 Timeline for Special PT (SPT) Activities

- May-October 2009 – NLCP HHS-Certified Laboratories will:
 - Validate new immunoassay tests for revised cutoffs and new analytes
 - Develop and validate confirmatory methods for revised cutoffs and new analytes
- November 2009 – NLCP will:
 - Send practice samples to Laboratories to allow verification of validations

2010 Timeline for SPT Activities

- January to March 2010 – NLCP will:
 - Send three rounds of qualifying SPT samples
 - Score and remediate results as required
- April 2010 – Additional SPT testing as required

2010 Timeline for SPT Activities

- May 1, 2010 (anticipated)– Revised regulations implemented
- Week 3 after Implementation – All Laboratories will receive limited set of SPT samples

Revised/ New Cutoffs

Analyte	Initial Cutoff (ng/mL)	Confirmatory Cutoff (ng/mL)
Benzoylecgonine	150	100
6-AM	10*	Unchanged (10)
MAMP	500	250**
AMP		250
MDMA	500*	250
MDA		250
MDEA		250

- ***New Immunoassay**
- **** \geq 100 ng/mL of AMP required for MAMP positives**

The Practice PT Set

- Objective: To provide samples for Laboratories to check the performance of their initial test and confirmatory test methods
- Focus: new analytes and analytes with revised cutoffs

The Practice PT Set: Composition

- 10-12 samples
- Containing drug analytes at 0.5x and 1.5x the IA cutoff
- Containing drug analytes at 1x and 2x the confirmatory cutoff concentrations

The SPT Sets

- Objectives: Prior to implementation of revised Guidelines
 - Verify the ability of Laboratories' test methods to meet new and revised requirements
 - Verify the ability of Laboratories to correctly report results in accordance with new and revised requirements
- Focus: New analytes at specified cutoffs and current analytes at revised cutoffs

The Special PT (SPT) Process I

- January 2010 – A set of 15-20 SPT samples will be sent to each Laboratory
 - Samples to be tested by immunoassay will contain MAMP, AMP, MDMA, MDA, MDEA, 6-AM and benzoylecgonine at and around the cutoffs prescribed in the revised Guidelines
 - Samples are to be tested using the laboratory's validated confirmatory procedures as directed by the NLCP

The Special PT Process II

- January 2010 SPT (cont)
 - All results obtained from IA and confirmatory testing must be returned to the NLCP for scoring within 5 days after receipt of SPT samples
 - Each laboratory will receive their Scored Results approximately 2 weeks after the results have been reported to the NLCP

The Special PT Process III

- Additional SPT sets will be sent in February and March 2010
- Focused SPT sets will be tested in April 2010 as necessary

The Special PT Process IV

- Laboratories:
 - Must demonstrate acceptable performance on each PT set as delineated in the Revised Guidelines
 - Failing to meet standards will require remediation of errors and demonstration of acceptable performance through testing of additional PT samples

The Special PT Process V

- Post Implementation
 - May 2010 (anticipated) - A set of PT samples challenging new analytes and revised cutoffs will be sent to all Laboratories within 3 weeks of the implementation to demonstrate continued acceptable performance

Immunoassay (IA) SPT Objectives I

- Determine:
 - Specificity
 - Performance at high analyte concentrations
 - Performance in presence of over-the-counter medications and other potential interfering and cross reacting compounds

Immunoassay (IA) SPT Objectives II

- Verify adherence to revised and new cutoffs
- Determine performance at $\pm 25\%$ of cutoff

Confirmatory SPT Objectives I

- Verify ability to identify and quantify the required analytes at the revised and new cutoffs
- Determine quantitative accuracy at analyte concentrations from 0.4x to 20x the cutoff

Confirmatory SPT Objectives II

- Verify performance in presence of over-the-counter medications and potential interfering compounds

Post Implementation PT Activities

- The Initial PT sets for IITFs will be available upon implementation of the revised Guidelines (anticipated May 1, 2010)
- The NLCP's MPT Program will resume in July 2010 incorporating challenges for all Drug and SVT testing as specified in the revised Guidelines