

Behavioral Health is Essential To Health



Prevention Works



Treatment is Effective



People Recover



Performance Testing Implementation Plan for the Revised Urine Guidelines

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Performance Testing Samples

- Practice Samples
- Special PT Sets
 - Pre-Implementation of revised Guidelines
 - Post-Implementation of revised Guidelines
- All PT samples in this presentation are based on the Notice of proposed revisions to the Mandatory Guidelines in the Federal Register May 15, 2015

The Practice PT Set (Open)

- **Objective:** To provide samples for laboratories to check the performance of their initial tests (immunoassays or alternate technologies) and confirmatory test methods
- **Focus:** new analytes (HYC, HYM, OXYC and OXYM) and added initial test analyte (MDA)
- **Timeline:** Laboratories will receive practice samples from the NLCP following publication of the revised Guidelines in the Federal Register

Practice Samples: Synthetic Opioids & MDMA Immunoassay/Confirmation

Sample #	HYC	HYM	OXYC	OXYM	MDMA	MDA	Comment
1	150						0.5X IT
2	375						1.25X IT
3	100						1X Conf
4		150					0.5X IT
5		375					1.25X IT
6		100					1X Conf
7			50				0.5X IT & 1X Conf
8			125				1.25X IT
9				50			0.5X IT & 1X Conf
10				125			1.25X IT
11					250		0.5X IT
12					625		1.25X IT
13						250	0.5X IT
14						625	1.25X IT

Pre-Implementation Qualifying PT Sets

- **Objectives:**
 - Verify that test methods to be used by certified laboratories and reported results are in accordance with revised Guidelines requirements
- **Focus:**
 - New analytes (HYC, HYM, OXYC and OXYM)
 - Added initial test analyte (MDA)
 - pH (low pH cutoff for adulteration change from less than 3 to less than 4)
- **Timeline:**
 - The first set is sent 4 months before revised Guidelines effective date

Qualifying PT Sets

- Laboratories receive three rounds of qualifying blind PT samples
- Each round is graded and remediated for errors
- Each set is sent about 1 month apart
- There is no cost to the laboratories for the PT samples

Qualifying PT Sets - Composition

- Each set is 10 samples
- Sample challenges are for HYC, HYM, OXYC, OXYM, MDMA, MDA, and pH
- Initial test challenges are for drug detection at targets of 1.25x and higher of the cutoff concentration

Qualifying PT Sets – Composition (Continued)

- Confirmatory drug challenges are for quantitative accuracy at analyte concentrations from 0.4x to 20x the cutoff concentration
 - Challenges at 0.4x confirmatory cutoff are to identify and quantitate the required analytes in the presence of potentially interfering compounds
 - codeine, morphine, and 6-AM concentrations up to 20x current confirmatory cutoff
 - noroxycodone, noroxymorphone up to 1,000ng/mL
 - norcodeine, norhydrocodone up to 4,000ng/mL

Qualifying PT Sets – Reporting & Scoring

- Laboratories report results to the NLCP within 5 business days after receipt via the NLCP PT website and submit completed CCFs
- Reported results are scored in accordance with the revised Guidelines
- Laboratories assessed Major Errors must remediate the error before receiving the next set of PT samples
- Each laboratory will receive their Scored Results approximately 2 weeks after the results from all laboratories have been reported to the NLCP

Qualifying PT Sets – Focused Samples

- Laboratories not meeting minimum Guidelines requirements will receive additional PT set(s)
- These focused sets will contain PT samples to assess effectiveness of corrective actions
- Laboratories must demonstrate acceptable performance before the Guidelines effective date

Post-Implementation Qualifying PT Set

- **Objective:** One set of PT samples to demonstrate the performance of certified laboratories for routine testing after the revised Guidelines have been implemented
- **Focus** (same as pre-implementation):
 - New analytes (HYC, HYM, OXYC and OXYM)
 - Added initial test analyte (MDA)
 - pH (raise the low pH cutoff for adulteration from less than 3 to less than 4)
- PT samples are scored by the NLCP and errors are remediated