PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

Urine collection, processing, and storage

The participant is asked to urinate into a sterile 90 ml urine specimen container. Specimen collection should be observed to prevent specimen adulteration or substitution. Specimens should be refrigerated immediately after collection and aliquoted into a 4 ml cryovial (for each drug type being tested) within 48 hours. Cryovials should be frozen at -20˚C until analysis. Specimens should be analyzed within 2 months of collection.

Cannabis

Enzyme immunoassay should be employed to detect the marijuana metabolite Δ9-tetrahydrocannabinol-9-carboxylic acid (THCCOOH). The assay will reliably detect marijuana metabolite concentrations greater than 50 ng/ml.

Gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis should be employed to accurately detect THCCOOH concentrations greater than 15 ng/ml.

Cannabis detection window

a) It has been reported that after occasional use, 11-nor-9-carboxy-Δ9-tetrahydrocannabinol (THCCOOH) concentrations in urine remain above 15 ng/ml after alkaline hydrolysis for up to 4 days (Huestis et al., 1996).

b) Urinary THCCOOH detection windows range from several days in infrequent users to months in frequent users (Ellis et al., 1985; Peat, 1989; Kelly & Jones, 1992; Fraser & Worth, 2003; Lowe et al., 2009).

c) Differentiating new cannabis use from prolonged urinary excretion in chronic users is difficult. Several mathematical approaches for identifying new cannabis use based upon creatinine corrected THCCOOH urinary concentrations have been reported (Huestis et al., 1998; Schwilke et al., 2011; Smith et al., 2009).

d) Research continues to identify biomarkers for directly distinguishing new

cannabis use (Skopp & Potsch, 2002; Mareck et al., 2009; Weinmann et al., 2000).

Cocaine

Enzyme immunoassay should be employed to detect the cocaine metabolite benzoylecgonine (BE). The assay will reliably detect cocaine metabolite concentrations greater than 300 ng/ml.

Gas chromatographic mass spectrometric (GCMS) or liquid chromatographic mass spectrometric analysis should be employed to accurately detect BE concentrations greater than 150 ng/ml.

Cocaine detection window

The Drugs of Abuse Reference Guide indicates the urine screening cutoff for cocaine detection is 300 ng/ml. National Institute of Drug Abuse (NIDA) clinical trials also use this concentration as the threshold. GCMS can confirm a concentration of 150 ng/ml or greater. The urine detection time is 2–5 days (Lab Corporation of America, 2007).

Amphetamine or methamphetamine

Enzyme immunoassay should be employed to reliably detect methamphetamine concentrations greater than 500 ng/ml.

Gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis should be employed to accurately detect methamphetamine concentrations greater than 250 ng/ml and amphetamine concentrations greater than 100 ng/ml. To be positive for methamphetamine, a specimen must exceed 250 ng/ml methamphetamine and contain more than 100 ng/ml of amphetamine.

Methamphetamine detection window

25–77 hrs after oral administration of a single 10 mg methamphetamine hydrochloride sustained release capsule methamphetamine and amphetamine urine concentrations exceeded 250 and 100 ng/ml, respectively (n = 5) (Oyler et al., 2002).

Opiates

Enzyme immunoassay should be employed to reliably detect morphine concentrations greater than 300 ng/ml.

Gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis should be employed to accurately detect codeine and morphine concentrations greater than 300 ng/ml.

Opiate detection window

The Drugs of Abuse Reference Guide indicates the urine screening cutoff for codeine and morphine detection is 300 ng/ml. National Institute of Drug Abuse (NIDA) clinical trials also use this concentration as the threshold. GCMS can confirm a concentration of 300 ng/ml or greater. The urine detection time is 2–3 days (Lab Corporation of America, 2007).

Methylenedioxymethamphetamine (MDMA, ecstasy), methylenedioxyamphetamine (MDA) or methylenedioxyethylamphetamine (MDEA)

Enzyme immunoassay should be employed to reliably detect MDMA concentrations greater than 500 ng/ml.

Gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis should be employed to accurately detect MDMA, MDA, and MDEA concentrations greater than 250 ng/ml.

MDMA detection window

Following a single 1.0 or 1.6 mg/kg oral administration of MDMA, urine specimens were unlikely to contain more than 250 ng/ml of MDMA for more than 48 hrs after dosing (n = 16) (Abraham et al., 2009).

Methadone

Enzyme immunoassay should be employed to reliably detect methadone concentrations greater than 300 ng/ml.

Gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis should be employed to accurately detect methadone and 2-ethylidine-1,5dimethyl-3,3-diphenylpyrrolidine (EDDP) concentrations greater than 100 ng/ml.

Buprenorphine (Suboxone)

Enzyme immunoassay should be employed to reliably detect norbuprenorphine, the metabolite of buprenorphine, at levels greater than 10 ng/ml.

Gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis should be employed to accurately detect buprenorphine at levels greater than 2 ng/ml.

Interpretation of Results

In general, a positive result, i.e., the presence of drug is detected in an enzyme

immunoassay, indicates that the individual has ingested the drug, or a drug in the same chemical class, within the window of detection. Not all positive drug screens are due to illicit drug use or are confirmed. Drugs taken in low doses or at times outside of the window of detection may not result in a positive drug screen.

Protocol source: https://www.phenxtoolkit.org/protocols/view/510701