DTPM
DRUG FREE WORKPLACE PROGRAM

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INDUSTRIAL TOXICOLOGY RECIEVING SOP

This document outlines the procedure for receiving samples for drug testing (POC, screening, and LC-MS/MS confirmation) by DTPM Industrial Laboratory.

DEFINITIONS TO KNOW:

Chain of Custody: Documentation of all people (donors, collectors, lab personnel, etc) who are in possession of the sample from collection through testing, and reporting of results.

Collector: Person(s) who ensure samples are collected according to the guidelines of this procedure and that chain of custody and sample security are maintained until the sample arrives at the Lab.

Confirmation: Definitive testing, usually by GCMS or LC-MS/MS that is performed to conclusively determine the identity and quantity of a drug or metabolite in the sample. Samples may include urine or oral fluids.

Donor: Person providing sample (urine or oral fluid) for drug testing. Must have verifiable identification that matches the testing order.

POC: Point of Care. This indicates that the collection device contains an integrated color change immunoassay that serves as an initial screen for the perspective drug at the specified cutoff.

PPE: Personal Protective Equipment. Includes items such as gloves, lab coat, safety glasses or face shield to prevent exposure to and cross-contamination of samples.

Sample: Urine or oral fluid sample provided for the purpose of toxicological analysis (drug screening and confirmation)

Screening: Initial testing, usually immunochemical techniques that determine the presence of a drug or metabolite above a certain predefined cutoff. Samples may include urine or oral fluids

Tech: Lab tech, chemist, or other personnel who perform toxicology testing.

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STEP BY STEP RECIEVING PROCESS

1. TESTING SITE REQUIREMENTS

a. At the time of receipt, Tech is to open the shipping container and ensure the following:

- ***i.*** Sample temperature is within the specified range
- ***ii.*** There is no evidence of spills or loss of sample
- ***iii.*** Appearance of each sample is normal
  1. No excessive foaming
  2. No precipitates or solids
  3. Color is typical and uniform
  4. No abnormal odor (bleach, ammonia, other chemicals)
- ***iv.*** Temper evident seal is intact and signed by both the Collector and the Donor
- ***v.*** Chain of Custody form contains all necessary information and matches the order in Phoenix

b. After each sample is found to be acceptable, it is logged into Phoenix and the barcode is printed.

c. One copy of the barcode is attached to the original sample container and one copy is attached to the Indiko sample tube (for screening samples) with the barcode facing out. For LCMS confirmation samples, the HPLC vial is labeled with the accession number if the sticker will not fit on the vial.

d. The testing site provides adequate PPE and washing facilities for the Tech.

e. Unauthorized personnel (including previous donors) are not allowed in the testing area unescorted or unannounced.

2. TESTING SITE SECURITY

a. The testing site is to be secure to prevent unauthorized access to specimens, testing supplies, and test records.

b. Unauthorized personnel are prohibited from entering the testing lab.

c. Chain of custody must be maintained and documented throughout the testing process. Samples are not valid for testing if chain of custody is not documented or verifiable. Never place a sample into an unlabeled container for testing (HPLC vial or sample tube). Verify that the accession number on the sample matches that on the vial of sample tube. If there are any mix-ups or discrepancies, the affected sample must be discarded and started from the beginning taking care to verify identity at each stage.

d. Ensure that the appropriate copies of the COC form is maintained by the testing site.

e. Ensure that samples are stored in a secure location during and after testing to prevent theft, loss, adulteration, or tampering. Tested samples are to be stored refrigerated for up to 10 days or current documented stability time in the testing SOP.

f. Ensure samples are stored and shipped at the appropriate temperature.

g. Ensure that samples are disposed of appropriately at the end of the storage time.

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3. SAFETY AND CONTAMINATION CONTROL

a. Prevention

i. Always work in a way that promotes safety. Be alert. Keep your workspace clean and organized. Know the hazards of each task and take precautions accordingly.

ii. Actively observe the work environment for safety improvements. Clear up any near misses, accidents, or other issues before they escalate or continue to further safety concerns.

iii. Take ownership of the work environment and discuss with coworkers and management ways to improve safety.

b. Accidents

i. Report any workplace accident immediately to management

ii. Determine the level of care needed (routine first aid such as band aids or further medical care)

c. Personal Protection Equipment (PPE)

i. The Tech wears appropriate PPE consisting of disposable exam gloves, lab coat, and eye protection (glasses, face shield, etc) as required and appropriate for each stage of sample handling

ii. Gloves are changed at each stage of testing

iii. Used PPE is not allowed outside of the collection area and must be disposed of in appropriate waste containers.

d. Spills

i. Spills are to be cleaned immediately

ii. Wipe up the liquid with paper towels or other absorbent material

iii. Spray the surface with disinfectant such as bleach or IPA

iv. Wipe up the disinfectant

v. Discard all towels and absorbents in the appropriate waste container

vi. Discard PPE used to clean the spill and replace prior to conducting further testing

e. Decontamination

i. Testing area is to be decontaminated between each set of tests

ii. Disinfect lab table by wiping up any visible liquid then spraying with bleach or IPA and wiping up the liquid. An absorbent cloth that will soak up any spill and is then discarded appropriately is recommended.

iii. Discard used PPE appropriately

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4. SAMPLE REJECTION

Samples will be rejected by for the following reasons:

a. Sample is not received at the appropriate temperature or within the appropriate time window

b. Paperwork is missing or contains discrepancies

c. Identification of both Donor and Collector are not discernable

d. Spills, leakage, or other issues that might lead to cross-contamination or otherwise call into question sample integrity

e. Sample appears to be altered, contaminated, or tampered with

f. Tamper-evident seal is broken or missing

g. Insufficient sample

h. Known swapping, tampering, or adulteration of sample by Donor either as witnessed by Collector or admitted by Donor

5. DOCUMENTATION ERRORS

The COC form is the ultimate document whose purpose is to ensure the security and integrity of the sample from collection until testing is complete. Errors in this document make it impossible to link the sample to the correct Donor and ensure that the sample has not been switched, altered, or otherwise adulterated by other parties. Errors are to be immediately corrected using the following procedure:

a. Make a single straight line through the erroneous entry so that the original entry is still legible.

b. Make the correct entry

c. Initial and date the change

Changes or alterations to COC documentation that are not properly performed may result in invalidation of the sample.

Samples received with illegible, unclear, or unacceptable write-overs or other error corrections may result in rejection of the affective sample.

6. DOCUMENTATION OF REJECTED SAMPLES

a. Samples that are rejected are logged into a Sample Rejection Log.

b. The COC form for each rejected sample is stored in a binder with an explanation of why it was rejected recorded clearly. Extra pages may be attached to the COC form if necessary to fully document reasons for rejection.