DTPM

DRUG FREE WORKPLACE PROGRAM

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INDUSTRIAL TOXICOLOGY COLLECTION 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.

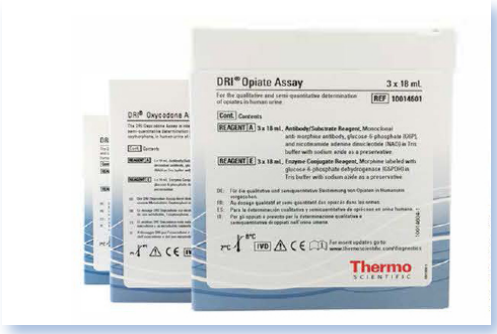
Confirmation: Definitive testing, usually by GCMS or LC-MS/MS that is performed to conclusively determine the identity and quantity of a drug or metabolite in the sample. Samples may include urine or oral fluids.

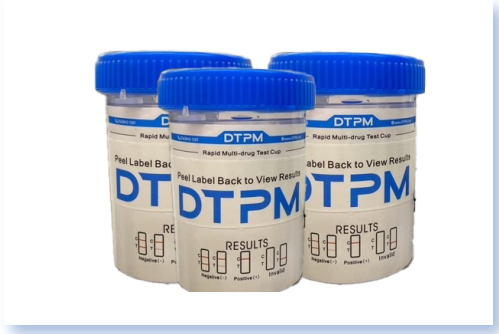
Donor: Person providing sample (urine or oral fluid) for drug testing. Must have verifiable identification that matches the testing order.

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.

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





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STEP BY STEP RECIEVING PROCESS

1. COLLECTION SITE REQUIREMENTS

a. At the time of arrival, the Donor must sign into a logbook recording their name, current phone number, and time.

b. The collection site will maintain a waiting area that provides privacy for Donors and security of samples and collection area.

c. Donors are not allowed into the collection area until the Collector is ready and all previous donors have exited.

d. After the collection process is completed, the Donor is to sign out of the logbook indicating the time of their departure.

e. The collection site provides adequate PPE and washing facilities for the Collector as well as the Donor. A handwashing station (eg, a sink, soap, and single-use paper towels), disinfecting handwipes, or waterless hand sanitizer is provided.

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

2. VERIFICATION OF DONOR IDENTITY

a. Acceptable forms of identification:

- ***i.*** Photo identification (Driver's license, employee ID badge, or any other photo ID issued by a federal, state, or local government)
- ***ii.*** Identification by a supervisor.

b. Unacceptable forms of identification

- ***i.*** Identification by a co-worker
- ***ii.*** Identification by another donor
- ***iii.*** Non-photo identification (social security card, birth certificate, credit card, pay stub, etc)
- ***iv.*** Faxed or electronic copies of photo identification documents

c. If the Collector can not verify the identity of the Donor, the Collector is to stop the collection process. In the event the sample is already collected, it is not valid and is to be discarded. Invalid samples are not to be shipped to the lab.

3. COLLECTION SITE SECURITY

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

b. Collection area is to be within line of sight of Collector at all times

c. Unauthorized personnel are prohibited from entering the collection site

d. Only one collection is to be performed at a time by any Collector. If multiple Collectors are working simultaneously, the must be sufficiently separated to ensure the integrity and privacy of Donors, supplies, records, and samples.

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e. Chain of custody must be maintained and documented throughout the collection process. Samples are not valid for testing if chain of custody is not documented or verifiable.

f. Ensure that the appropriate copies of the COC form is maintained by the Collector site and the appropriate copy is given to the Donor for their records.

g. Ensure that tamper evident seals are sealed and initialed by both the Donor and Collector.

h. No one is to have access to samples until tamper-evident seal and other documentation is completed

i. Ensure that samples are stored in a secure location after collection to prevent theft, loss, adulteration, or tampering.

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

k. Maintain tracking numbers and any other shipping records for each sample.

l. Ensure that samples are transported to the test facility in sealed, secure shipping containers. Damage during shipping can result in contamination or loss of samples.

m. Restrict access to collection supplies before and during the collection

- ***i.*** Remain in collection area until all collection is complete
- ***ii.*** Do not leave samples or supplies unattended for any reason
- ***iii.*** Ensure that Donors leave the collection area as soon as collection and documentation is completed

4. COLLECTION SUPPLIES

a. Single-use collection cups (POC cups, urine collection cups, specimen bottles, etc)

b. Temperature strips (if not integrated into collection cup)

c. Tamper-evident labels/strips (if not integrated into collection cup)

d. Leak-resistant plastic bag

e. Absorbent material

f. Shipping supplies (temperature-controlled containers, cooling packs, shipping labels, etc)

g. Bluing agent

h. Exam gloves and eye protection

i. Oral fluid or collection kits

5. 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.

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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. Collection area is to be decontaminated between each Donor

ii. Flush toilet and clean any liquid from the commode with an appropriate disinfectant

iii. Disinfect handles and knobs

iv. Disinfect collection table by wiping up any visible liquid then spraying with bleach or IPA and wiping up the liquid

v. Discard used PPE appropriately

6. COLLECTION PROCEDURE – URINE SAMPLES

a. Ensure that all required collection supplies are present prior to beginning the collection process

b. Turn off water supply

c. Remove soaps, disinfectants, cleaning materials, and other potential adulterants

d. Begin collection immediately when Donor arrives.

e. Verify and document Donor identity

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f. Provide instructions on the donation process and ensure Donor understands them

g. Answer any questions the Donor has

h. Complete all Collector sections of the COC form in the presence of the Donor. Have Donor complete the relevant Donor sections of the COC form in Collectors presence.

i. Have Donor to empty pockets and remove jackets, hats, etc that might be used to hide adulterants or false samples

j. Leave personal belongings (purse, briefcase, etc) that might be used for concealment with outer wear

k. If Donor refuses to reveal contents of pockets or other garments or otherwise demonstrate no intent to adulterate sample, stop collection and document accordingly.

l. Donor enters stall or other collection location and provides sufficient sample, caps the collection vessel, and brings it to the designated area.

m. Instruct the Donor to:

- ***i.*** Take the collection container into the stall
- ***ii.*** Provide a specimen between the minimum and maximum fill lines of the DTPM POC cups (45-60 mL if other cups are used)
- ***iii.*** DO NOT flush the toiled
- ***iv.*** Return the specimen immediately after collection. They may complete emptying their bladder, but the temperature of the sample must be recorded within 4 minutes. If temperature is out of range, the sample is not valid and must be discarded.
- ***v.*** Both Donor and Collector maintain sight of the sample until the tamper-evident seal is affixed and signed by both parties.

n. Collector verifies the following:

- ***i.*** Temperature is within range
- ***ii.*** Sample color is normal
- ***iii.*** No foreign material or foaming is present
- ***iv.*** No unusual odor (bleach, ammonia, etc)

o. Collector affixes tamper-evident label to the sample container in the presence of Donor and both Donor and Collector initial the label.

p. Donor is allowed to wash hands after completing the collection process

q. All personal items and clothing are returned to Donor

r. Donor and Collector complete the relevant sections of the COC form and any other required documentation.

s. The Donor copy of the COC form and other paperwork is provided to the Donor and he or she is allowed to leave the collection site.

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7. COLLECTION PROCEDURE – ORAL SWAB SAMPLES

a. All oral fluid collection activities are to be performed in the presence of and line of site of the Collector.

b. Provide the Donor with the swab and other necessary collection materials.

c. Go over the manufacture's instructions with them. Ensure they understand the collection procedure.

d. Answer any questions they have.

e. Once they understand the procedure, instruct Donor to provide the sample using the prescribed instructions.

f. Once collection is complete, read the results (in the case of POC testing). If any assays indicate the presence of a tested drug, seal, package, and ship the associated sample to the lab for confirmation testing.

g. If the swab is not a POC (with integrated color change tests), seal, package, and ship the associated sample to the lab for screening and/or confirmation testing.

h. Complete all COC and other related paperwork in the presence of the Donor.

i. Attach tamper-evident label to the sample.

8. SAMPLE PACKAGING

a. Samples are to be tightly sealed and stored individually in sealed, leak-proof secondary containers (such as a biohazard bag) containing an absorbent material.

b. Samples are shipped in temperature-controlled shipping boxes with an appropriate cold pack

c. Samples are to be shipped within 24 hours of collection

9. 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

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10. COLLECTOR 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 in the presence of the Donor 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.

11. REFUSAL TO TEST

a. Failure or refusal of the Donor to provide a sample according to any of the above guidelines or other suspicious activity that violates the traceability or integrity of the sample is considered a refusal to test. Only the guidelines above are suitable for providing a valid sample and must be adhered to by both the Donor and Collector.

b. Other causes for recording "Refusal to Test" include but are not limited to:

- ***i.*** Donor fails to cooperate with any part of the above process
- ***ii.*** Donor refuses to provide sufficient sample
- ***iii.*** Donor leaves collection site without completing COC and any other documentation
- ***iv.*** Donor makes statements or exhibits behavior that indicates that he or she has adulterated or substituted his or her sample
- ***v.*** Donor brings sample from outside into the testing site

c. If a Donor refuses to provide sample according to the above guidelines, the incident is documented appropriately, and the Donor must leave the collection site. Any evidence of adulteration or switching of sample must be maintained and the incident must be reported immediately to the referring employer, treatment facility, MRO, or other relevant personnel.