PROCEDURE: DRUG OF ABUSE

**General information**

1) Should you intend to operate a collection site for drug testing, we recommend that you contact CDL Laboratories to elaborate a Standard Operating Procedure (SOP) specific to your site, needs and requirements.

2) CDL procedures coincide with the National Institute on Drug of Abuse (NIDA) and Substance Abuse and Mental Health Service Administration (SAMSHA). Furthermore, CDL Laboratories is enrolled in several strict external quality control programs to ensure total quality of results and procedures.

3) Integrity and conformity of the specimen are two critical factors in the drug of abuse testing process.
   - Integrity means that CDL can demonstrate that the specimen to be analyzed is a real urine sample. In order to do so, we have to be able to always track how and by whom the specimen was handled. CDL’s responsibility starts when the specimen is transferred to our personnel.
   - Conformity means that the specimen is compliant with CDL quality standards. Conformity is essential because we will not analyze a specimen that does not comply with our quality standards. CDL may report suspicious specimens (abnormal results, diluted, substituted or adulterated specimens) to a medical review officer (MRO).
   - CDL Laboratories is responsible for the integrity of the specimen only when collection is done at CDL clinics.

**Medical supplies**

- CDL sterile split collection kit (SAMHSA) (see Figure 1):
  - One container for sample collection with temperature reading indicator;
  - 2 vials (one for screening and the other for confirmation);
  - Absorbent paper;
  - Biohazard bag.
- Drug of abuse Chain of Custody form CF400 001 (mandatory);
- Pre numbered labels are available upon request;
- Stability:

**Drugs:**

- 24 hours at room temperature 15 – 25 ºC
- 3 days refrigerated 2 – 8 ºC
- 2 months frozen -20 ºC

**Urine analysis:**

- Less than 2 hours at room temperature
- Less than 6 hours refrigerated
Requirements for the collection site

Note: An observer is a direct witness to the collection process (donor and observer in the same stall) as opposed to a monitor who supervises the collection site (monitor supervising outside the stall).

1) Ensure that you have all necessary materials, equipment, facilities and supervision for the collection, temporary storage, and shipping of urine specimens to CDL Laboratory.

2) Your facility has to correspond to one of the two options described below:
   - The preferred type of facility includes a single-toilet room with a full-length privacy door:
     - Only the donor may be present in the room during the collection, except for the observer in the event of a directly supervised collection (usually following MRO recommendation).
     - Have a source of water for washing hands that, if practicable, should be external to the closed room. If an external source is not available, you may meet this requirement by securing all sources of water and other substances that could be used for adulteration, dilution or substitution (e.g., water faucets, soap dispensers) and provide moist towelettes outside the closed room.
   - The second type of facility is a multi-stall restroom that provides substantial visual privacy (e.g., a toilet stall with a partial-length door) and meets all requirements of this section:
     - Secure all sources of water and other substances that could be used for adulteration, dilution or substitution (e.g., water faucets, soap dispensers) and place blueing agent in all toilets or secure the toilets to prevent access;
     - No one but the donor and the monitor may be present in the multi-stall restroom during the collection, or the observer in the event of a directly supervised collection.

Instructions for the collector

1) As the collector, you must do the following before each collection to deter tampering with specimens:
   - Secure any water sources or otherwise make them unavailable to the donor (e.g., turn off water, tape handles to prevent opening faucets).
   - Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present.
   - Inspect the site to ensure that no foreign or unauthorized substances are present.
   - Tape or otherwise secure shut any movable toilet tank, or put blueing in the tank.
Verify the following areas (that may appear suitable for concealing contaminants (e.g., ledges, trash bins, paper towel holders, under-sink areas).

Recheck items of this section following each collection to ensure the site’s continued integrity.

2) If the facility is normally used for other purposes, like a public rest room or hospital examining room, you must also ensure before the collection that:
   - Access to collection supplies and specimens is effectively restricted.
   - The facility is secured against access during the procedure to ensure privacy to the donor and prevent distraction.

3) As the collector you must read and understand the additional steps described in this procedure in order to ensure security during the collection process:
   - When operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored.
   - Remove any person who obstructs, interferes with, or causes a delay in the collection process.
   - Minimize the number of persons handling specimens.
   - Conduct a collection for only one donor at a time.
   - Ensure you are the only person, in addition to the donor, who handles the specimen before it is poured into another container if applicable. Use only the specific drug of abuse collection kit.
   - Maintain personal control over each specimen and Drug of abuse chain of custody form throughout the collection process.

Collection

Perform all steps in front of donor.

1) Verify patient identity with a card that has a picture;
2) Ask the donor to either choose a collection kit or open it in front of the donor;
3) Open the collection kit and take out the material inside the main urine collection container;
4) Give the donor a urine collection procedure to read (a procedure is indicated at the end of this section);
5) Place the pre numbered labels on the Chain of Custody form or fill out the form indicating:
   - Doctor’s name and/or your clinic;
   - Donor’s first and last name or coded identification number;
   - Telephone number (optional);
   - Gender;
   - Donor’s ID coordinates (only if identification of the donor is not coded);
   - Date of birth;
   - Requested drug(s) to be tested (if not already indicated);
   - List the drugs consumed within the last 14 days.
6) Reconfirm that the patient agrees with this collection procedure;
7) Ask the donor to leave his coat, bags or belonging outside of the urine collecting room;
8) Place the pre numbered labels on the urine container and the 2 vials A and B or identify with both:
   - First and last name;
   - Date of birth or Medicare number.
9) Put on gloves;
10) Ask the donor to wash his/her hands;
11) Give the urine container to the donor and ask for as much urine as possible (a minimum of 45 mL total is necessary);
12) Take the sample back from the donor immediately;
13) Verify that the sample ID is the same as the requisition and the Chain of Custody form;
14) Verify sample appearance, color and odour;
15) Transfer the urine in the 2 vials. Vial A is for screening and requires a minimum of 30 mL. Vial B is for confirmation and requires a minimum of 15 mL;
16) Close the containers tightly;
17) Place the 2 vials in the Biohazard bag and seal;
18) Indicate date and time of collection on the Chain of Custody Form;
19) Have the donor initial and date the information on the specimen bottle;
20) Have the donor sign and date and time the Chain of Custody Form as for transferring the specimen to you;
21) Indicate on the Chain of Custody Form:
   ▪ Temperature reading taken within 4 minutes;
   ▪ That the urine temperature is between (32.0 – 38.0) ºC or (90.0 – 100.0) ºF. If not, record body temperature. If body temperature is normal, ask for another sample;
   ▪ Color and clarity;
   ▪ Approximate volume of urine collected;
   ▪ Sign and date and time.
22) Fill-out each column of the first line of the table;
23) Have the Doctor or an authorized representative sign the form;
24) Give the 3rd copy of the Chain of Custody Form to the donor;
25) Place the Chain of Custody form in the external pocket of the Biohazard bag;
26) Refrigerate;
27) Contact CDL Laboratories about transportation if you are not using our CDL courier for this procedure;
28) Include ice packs in the shipping in order to keep samples between 2 – 8 ºC during transportation.

Collection procedure for the donor

1) Wash your hands with soap and water;
2) Start urinating in the toilet and then stop;
3) Continue to urinate in the collection container. Provide a minimum of 45mL of urine;
4) Finish urinating in the toilet if necessary;
5) Give back the container immediately to the designated collector (e.g. nurse).

Additional information

1) When ordering a urine drug test at CDL, additional parameters are included in order to confirm conformity of the specimen including urinalysis and creatinine;
2) Additional tests (non related to drug testing) must be performed on a separate specimen;
3) Results will only be communicated to authorized personnel;
4) A test confirmation will be recommended if applicable and will be performed following authorization only.