

Specimen Handling and Collection

Instructions for patients

Overview

This document provides specific instructions for the patients made available at the referring laboratory and the laboratory website for proper collection of samples for testing Toxicology.

Instructions for Collection

The collection must meet the following security requirements by having:

1. Procedures to prevent the patient or anyone else from gaining unauthorized access to the collection materials/supplies.
2. The collector must also ensure that the patient does not have access to items that could be used to adulterate or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water).
3. Procedures to ensure that all authorized people are always under the supervision of a collector or appropriate site personnel when permitted into the site; and,
4. Procedures to provide for the secure handling and storage of specimens. The following items must be available at the collection site to conduct proper collections:
 - a. For each test, a collection kit meeting the requirements consists of a specimen cup with a temperature strip.
 - b. Requisition form provided by the laboratory.
 - c. Bluing (coloring) agent added to the toilet bowl/water tank to prevent a patient from diluting the specimen.

The collector must do the following before each collection to deter potential tampering, adulteration, alteration, or substitution of the specimens:

1. Secure warm water sources or otherwise make them unavailable to patients (e.g., turn off water inlets, Tape handles to prevent opening warm water faucets).
2. Ensure that the water in the toilet and tank (if applicable) has bluing (coloring) agent in it. Tape or otherwise secure shut any movable toilet tank top or put blue in the tank.
3. Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are available to the patient.
4. Inspect the site to ensure that no foreign or unauthorized substances are present.
5. Ensure that undetected access (e.g., through a door not in your view) is not possible.
6. Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and
7. Recheck items (1) through (6) after each collection to ensure the site's continued integrity. The following steps describe a typical urine collection procedure:

The collector prepares the collection site to collect urine specimens. All collection supplies must be available, the area properly secured, water sources secured, and bluing (coloring) agents placed in all toilets as specified in Sections 2 and 3 of these guidelines.

The collector explains the basic collection procedures to the patient.

The collector directs the patient to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen.

The collector instructs the patient to wash and dry his or her hands, under the collector's observation, and informs the patient not to wash his or her hands again until after the patient provides the specimen to the collector.

The collector gives the patient the collection kit or collection container (if it is separate from the kit) from the available supply. Either the collector or the patient, with both present, then unwraps or breaks the seal of the kit or collection container.

The collection container must still be sealed or individually wrapped in a plastic bag or shrink wrapping; or must have a peelable, sealed lid or other easily visible tamper-evident system. Do not unwrap or break the seal on any specimen bottle at this time. Unwrap only the collection container. The collector directs the patient to go into the room used for urination, provide a specimen of at least 45 mL, not to flush the toilet, and return with the specimen as soon as possible after completing the void.

Unless specifically indicated, “clean catch” procedures outlined below are optional.

The presence of blood in the urine sample may adversely impact the testing process and, in addition, constitutes a biohazard for laboratory employees. Collection of “clean catch” urine specimens during menstruation should be attempted.

Clean Catch Collection – Female Patient:

1. If menstruating, insert a fresh tampon to halt flow.
2. Open the sterile specimen collection cup without touching the rim, inside of the cup, or the inner surface of the cup lid.
3. Wash hands with soap and water. Dry hands.
4. Separate the skinfold around the urinary opening with one hand and keep apart until finished collecting the sample.
5. Using a sterile moist towelette (or cotton balls soaked in soap and water) wash the urinary opening and surrounding tissue, front to back. Rinse with clear water.
6. Begin urinating into the toilet, holding skin folds apart with your fingers.
7. After the urine stream is well established, and without interrupting the urine flow, move the sterile container into the path of the stream to "catch" the urine.
8. Collect the urine until the container is approximately half full (or until flow of urine decreases substantially) and then finish voiding into the toilet.

Clean Catch Collection – Male Patient:

1. Open the sterile specimen collection cup without touching the rim, inside of the cup, or inner surface of the cup lid.
Wash hands with soap and water. Dry hands.
3. Retract the foreskin and thoroughly wash the end of the penis using a sterile moist towelette or washcloth soaked in soapy water. Rinse with clear water.
4. Begin urinating into the toilet.
5. After the urine stream is well established, and without interrupting the urine flow, move the sterile container into the path of the stream to "catch" the urine.
6. Collect the urine until the container is approximately half full (or until flow of urine decreases substantially) and then finish voiding into the toilet.

These procedures will be explained on a sign posted in the restroom.

The collector should pay close attention to the patient during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen.

After the patient gives the specimen to the collector, the collector must check the temperature of the specimen, check the specimen volume, and inspect the specimen for adulteration or substitution. The collector should check the temperature of the specimen as soon as the patient hands over the specimen, but

no later than four minutes after the patient comes out of the restroom. The acceptable temperature range is 32°-38°C/ 90°-100°F.

Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container. If the temperature is within the acceptable range, the "Temperature" box is marked in on the requisition form indicating "Warm" or "In range", and the collector proceeds with the collection procedure. (If the temperature is out of range, the collector marks the "Out of range" box and initiates an observed collection.) The collector then checks to make sure that the specimen contains a sufficient amount of urine (a minimum of 45 mL for all DOT collections).

The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. If it is apparent from this inspection that the patient has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach), a second collection using direct observation procedures must be conducted immediately.

After the patient hands the collection container to the collector (and the collector checks the temperature), the collector may permit the patient to wash his or her hands.

The tamper-evident seal is then removed from the requisition form and placed on the bottle, ensuring that the seal is centered over the lid/cap and down the sides of the bottle to ensure that the lid/cap cannot be removed without destroying the seal. Since the specimen bottle is now sealed with tamper-evident tape and does not have to be under the patient's direct observation, the patient may wash his or her hands if he or she desires to do so.

The collector directs the patient to read, sign, and date the certification statement, and provide date of birth, printed name, height, weight, medications, and contact information on the requisition form.

The collector then ensures that all copies of the requisition are legible and completed.

The specimen bottles and one copy of the requisition form are placed inside the appropriate pouches of the leak-resistant plastic bag, and both pouches are sealed. If the patient has not had the opportunity to wash his or her hands, they may do so now. The collector then informs the patient that the collection process is complete.

The collector or collection site must ensure that each specimen collected is shipped to a laboratory as quickly as possible. If the specimen is not shipped immediately, the collector is responsible for ensuring its integrity and security in a refrigerator or freezer. Specimens in plastic bags, which have not been placed into shipping containers, or which are awaiting a laboratory courier, must be kept in a secure location. The specimens need not be under lock and key; however, procedures must exist that would ensure specimens cannot be subject to tampering.

Note: After specimens are placed into shipping containers that are subsequently sealed, the containers may be placed with other containers or packages that the collection site has waiting to be picked up by a courier or placed in a designated drop box used by a place the specimens into a commercial delivery system. Reasonable security measures will be used to ensure that all packages are relatively secure and not subject to damage, theft, or other actions that would potentially raise questions related to the integrity of the specimens. Specimens must be shipped in a manner to minimize damage in transit.

Special issues with collection.

Temperature

The collector should check the temperature of the specimen as soon as the patient hands over the specimen, but no later than four minutes after the patient comes out of the restroom. The acceptable temperature range is 32°-38°C/ 90°-100°F. Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container after the patient hands the specimen to the collector.

Adulteration or substitution

The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering or adulteration. If it is apparent from this inspection that the patient has adulterated or substituted the specimen (e.g., The specimen is blue, exhibits excessive foaming when shaken, has the smell of bleach), a second collection using direct observation procedures must be conducted immediately. The first specimen and the second specimen collected using direct observation are both sent to the laboratory for testing.