CHAPTER 6

LABORATORY PROCEDURE FOR SPECIMEN HANDLING

A DOH – accredited laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all laboratory operations pertaining to specimen handling. When followed, it ensures that all specimens are tested using the same procedure and in a consistent manner.

6.1. Observed Specimen Collection for Urine

Observed samples are collected in the presence of the Authorized Specimen Collector.

6.1.1 The Preliminary procedures for specimen collection.

The Authorized Specimen Collector shall:

6.1.1.1 Prepare and secure all collection supplies, materials and record

6.1.1.2 Verify the Client/Donor/Subject’s Identification

6.1.1.3 Explain the basic collection procedure to the Client/Donor/Subject;

6.1.1.4 Answer any reasonable and appropriate questions the Client/ Donor/Subject may ask regarding the collection procedure.

6.1.2 Basic steps in collecting urine specimen for drug testing:

6.1.2.1 The Client/Donor/Subject removes all unnecessary outer garments (such as coat or jacket), after which, he/she will be subjected to a bodily search.

6.1.2.2 The Authorized Specimen Collector directs the Client/Donor/Subject to empty his/her pockets and checks items that may be used to adulterate the specimen.

6.1.2.3 The Client/Donor/Subject washes and dries hands prior to collection. After washing hands, the Client/Donor/Subject must remain the presence of the Authorized Specimen Collector and must not have access to anything that could be used to affect the specimen.

6.1.2.4 The Authorized Specimen Collector either gives or allows the Client/Donor/Subject to select the collection container from the available supplies. The specimen container is opened in full view of the Client/Donor/Subject.

6.1.2.5 The Authorized Specimen Collector directs the Client/Donor/Subject to go in the toilet facility for urination and to provide at least 60 – ml either collected in single or split specimen.
6.1.2.6 The Authorized Specimen Collector shall observe closely the entire collection procedure and take note of the conduct and demeanor of Client/Donor/Subject for attempts of substitution adulteration and dilution of specimen.

6.1.2.7 A tampered specimen is sent to the laboratory for validity testing and the Authorized Specimen Collector shall document the tampering on the CCF with appropriate remarks. The Authorized Specimen Collector shall instruct the Client/Donor/Subject to provide another urine specimen immediately, under direct observed collection. This second specimen shall also be sent for examination.

6.1.2.8 After the Client/Donor/Subject hands the specimen, the Authorized Specimen Collector must measure the temperature, check the volume and inspect its physical characteristics.

6.1.2.9 The Authorized Specimen Collector and Client/Donor/Subject must keep the specimen in full view at all times prior to sealing of all specimen containers.

6.1.2.10 A tamper – evident label / seal must be used to secure the entire specimen container.

6.1.2.11 Both Authorized Specimen Collector and Client/Donor/Subject must affix their signature on the seal together with the date and time of collection.

6.1.2.12 The Authorized Specimen Collector must complete steps 1 and 2 and initiates step 4 of CCF.

6.1.2.13 The Client/Donor/Subject must affix his/her signature at Step 5 of the CCF. The Authorized Specimen Collector may ask the Client/Donor/Subject to list any prescription, medication he/she may have taken for the past two weeks at the back of the CCF (Analyst copy). Authorized Specimen Collector shall distribute each copy as required.

6.1.2.14 In case of specimen collection at a remote site and transport via a courier/mail, the specimen container together with the CCF shall be placed in a sealed, labelled and secured transparent plastic bag.

Note: Protocol for collection for other types of specimen shall be determined in a later publication.
6.1.3 Visual Privacy requirements when collecting a specimen

6.1.3.1 For urine specimen:
A laboratory must have the required restroom/stall with toilet for the Client/Donor/Subject to have privacy while collecting the urine specimen.

6.1.3.2 For scalp hair specimen:
The Authorized Specimen Collector shall collect available scalp hair 1 cm. above the scalp from the Client/Donor/Subject at a designated area.

6.1.3.3 For sweat specimen:
The sweat patch is applied to the Client/Donor/Subject's upper arm, chest, or back and removed by the Authorized Specimen Collector at a designated area.

6.1.3.4 For blood specimen:
At least 5 ml whole blood is extracted from Client/Donor/Subject placed in a 10 - ml capacity test tube without anticoagulant at a designated area.

6.1.3.5 For saliva (oral fluid)/ tissue/fingernails specimen:
The “neat” saliva (oral fluid)/tissue/fingernails specimen is collected directly into an appropriate container by the Client/Donor/Subject under the direct observation of the Authorized Specimen Collector at a designated area.

6.2 Unobserved Specimen Collection:
Unobserved samples are collected in the absence of Authorized Specimen Collector or submitted samples that are not collected at the collection site or laboratory. Unobserved samples are subject to specimen validity test.

Conditions when unobserved specimen collection is allowed. When the Client/Donor/Subject is:
1. Physically unable to go the laboratory or designated collection site
2. Involved in crime scene
3. Involved in post – accident
4. Critically ill

6.3 Integrity of Urine Specimen
The Authorized Specimen Collector must adopt procedures to minimize the risk of adulteration, substitution or dilution of the specimen during the collection procedure. The following precautions shall be taken to ensure the integrity of the specimen:

6.3.1 To deter the dilution of specimen at the collection site, toilet water coloring agents should be placed in toilet tanks or in the toilet bowl. Any other sources of water in the enclosure where urination occurs (e.g. taps, showers) will be secured prior to collection.
6.3.2 The Authorized Specimen Collector will ask the Client/Donor/Subject to remove any unnecessary outer garments such as coat or jacket that might conceal items or substance that could be used to tamper with or adulterate the Client/Donor/Subject’s urine specimen. He/She shall be subjected to bodily search. The Authorized Specimen Collector will ensure that all personal belongings such as purse or briefcase remain with the outer garments.

6.3.3 The Client/Donor/Subject will be instructed to wash and dry his/her hands prior to urination. After washing hands, the Client/Donor/Subject will remain in the presence of an Authorized Specimen Collector and will not have access to any unregulated source of water, soap dispenser, cleaning agent, or any other materials that could be used to adulterate the specimen.

6.3.4 The Authorized Specimen Collector will give or the Client/Donor/Subject will choose a clean specimen container from the available supplies. The Client/Donor/Subject will provide his/her specimen in the privacy of a toilet cubicle or otherwise partitioned area that allows for individual privacy. The Client/Donor/Subject will be instructed not to flush the toilet until the specimen is handed to Authorized Specimen Collector.

6.3.5 Upon receiving the specimen from the Client/Donor/Subject, the Authorized Specimen Collector will:

6.3.5.1 Check the volume of urine in the specimen container
6.3.5.2 Check the temperature of the urine specimen
6.3.5.3 Inspect the specimen to determine its color and appearance for any signs of contaminants. Any unusual findings will be noted on the Custody and Control Form.

6.3.6 Both the Client/Donor/Subject and the Authorized Specimen Collector will keep the specimen container/ specimen bottles in view at all times prior to the urine specimen being sealed and labeled.

6.3.6.1 The specimen bottle will have an Identification label that contains pertinent information such as date and time of specimen collection, signatures of the Client/Donor/Subject and Authorized Specimen Collector and specimen ID number.
6.3.6.2 The Authorized Specimen will fill – up steps 1 and 2 and initiates Step 4 of the Custody and Control Form and pack together with the urine specimen immediately for dispatch to the analytical laboratory.
6.4 Specimen rejection and cancellation of tests

All rejected specimens should be reported to the Head of the Laboratory stating the reason(s) of rejection.

6.4.1 Criteria for specimen rejection that are non–correctable

6.4.1.1 Incompatibility of the ID number on the specimen received by the laboratory with the number on the CCF.

6.4.1.2 Absence of ID number on the specimen.

6.4.1.3 No printed Authorized Specimen Collector’s name and signature on the CCF.

6.4.1.4 Broken or tampered seal on the specimen container.

6.4.1.5 Insufficient quantity of specimen.

6.4.2 Criteria of specimen rejection that is correctable

6.4.2.1 Failure of the Authorized Specimen Collector to sign CCF.

6.4.2.2 Failure to check and record the specimen temperature with appropriate remarks.

6.4.3 Appropriate remedial measures for correctable errors:

6.4.3.1 All errors must be properly documented, recorded in a Memorandum For Record (MFR) and duly signed by the Authorized Specimen Collector.

6.4.3.2 If the Authorized Specimen Collector’s signature cannot be corrected by a Memorandum for Record (MFR), the laboratory must report the specimen rejected for testing and provide a reason on the report.

6.4.3.3 If the Authorized Specimen Collector cannot provide an MFR to attest to the fact that he or she did measure the specimen temperature, the laboratory may report the test result for the specimen but indicate that the Authorized Specimen Collector could not provide an MFR to recover the omission.
6.5.4 Conditions that will not cause specimen rejection or cancellation of test

6.5.4.1 At the receiving area:

(a) Discrepancies of the laboratory name and address;
(b) Incomplete / incorrect / unreadable employer name or address;
(c) Name of the Head of the Laboratory is not indicated;
(d) Incomplete / incorrect address of the Head of the Laboratory
(e) Incorrect entry of the Client/Donor/Subject’s ID number;
(f) Unmarked “reason for test” box;
(g) Unmarked “drug tests to be performed” box;
(h) The collection site address is not indicated;
(i) Unmarked “specimen collection” box;
(j) Unmarked “observed” box (if applicable)
(k) The date and time of collection is not indicated;
(l) Incorrect entry of name of delivery/courier service; or
(m) The Client/Donor/Subject’s name inadvertently appears on laboratory copy of the CCF or on the tamper – evident labels used to seal the specimen bottles.

6.5.4.2 Within the laboratory:

(a) Failure to print and sign the Accessioner’s name;
(b) Failure to print and sign the Analyst’s name
(c) The Analyst accidentally initials the CCF rather than providing a signature for a non – negative result (Analyst’s initials are acceptable for a negative result);
(d) The Accessioner fails to mark one of the “primary specimen bottle seal intact” boxes, but the laboratory reported a “rejected for testing” result with an appropriate comment on the “Remarks” line.

Note: The above errors, omissions, and discrepancies are considered insignificant only when they occur less than one percent of the time. The expectation is that each trained Authorized Specimen Collector and accredited laboratory will make every effort to ensure that the CCF is properly completed and that all information is correct. When an error occurs more than one percent of the time, the Head of the Laboratory must direct the Authorized Specimen Collector or laboratory personnel (whichever is responsible for the error) to immediately take corrective actions to prevent the recurrence of the error.
6.5.4.3 Situations/errors that may require the Head of the Laboratory cancel a test

(a) The Client/Donor/Subject’s signature is missing on the Laboratory copy of the CCF and the Authorized Specimen Collector failed to provide a comment that the Client/Donor/Subject refused to sign the form;

(b) The Analyst failed to sign the CCF for a specimen being reported drug positive, adulterated, substituted, rejected for testing, invalid test result; or

(c) The electronic report provided by the laboratory does not contain all the data elements required for the DOH standard electronic laboratory report for a specimen being reported drug positive, substituted, rejected for testing, or invalid test result.

6.5.4.4 Corrective measures that the Head of the Laboratory must do prior to cancellation of the test in the above situation

(a) The Head of the Laboratory must contact the Authorized Specimen Collector to obtain a statement to verify that the Client/Donor/Subject refused to sign the Laboratory copy. If the Authorized Specimen Collector cannot provide such a statement, the Head of the Laboratory must cancel the test.

(b) The Head of the Laboratory must obtain a statement from the Analyst that he or she inadvertently forgot to sign the CCF, but did, in fact, properly conduct the certification review.

(c) The Head of the Laboratory must require the laboratory to modify and retransmit a corrected electronic report.

6.5. Conditions for retention of specimen

6.5.5.1 A laboratory must retain a specimen that was reported as negative for a minimum of five days after receipt of result.

6.5.5.2 A laboratory must retain a specimen that was reported either as positive, adulterated, substituted or invalid result for a minimum of 15 days upon receipt of the result. A specimen may be retained for a maximum of 1 – year upon request. If no such request is received, a specimen may be discarded.

6.5.5.3 A retained specimen must be kept in a secured location appropriately, to ensure its availability for any necessary retesting during an administrative or judicial proceeding.
6.6 Tests for additional drugs

Specimen can be tested for additional drugs upon request, depending on the service capability of the drug testing laboratory. However, when a laboratory performs a procedure to test specimen for which it is not accredited, it must inform the Client/Donor/Subject that the specimen is not being tested under the Guidelines and the procedures are not subject to review by the NRL.
CHAPTER 7

LABORATORY SECURITY AND CHAIN OF CUSTODY

The laboratory must provide an outline regarding chain-of-custody procedures during accessioning/receiving, aliquoting, initial and confirmatory testing, and disposition of specimen and aliquots consistent with the laboratory’s actual procedures.

7.1 Chain of Custody

7.1.1 Drug Testing Custody and Control Forms

7.1.1.1 Health Facilities and Services Regulatory Bureau (HFSRB) approved Drug Testing Custody and Control Form (CCF) must be used to document the collection of a specimen by all drug testing laboratories.

7.1.1.2 The form is used to document chain of custody from the time a Client/Donor/Subject gives the specimen to the Authorized Specimen Collector until the specimen is received for testing.

7.1.1.3 The CCF used for each type of specimen collected should be available at the drug testing laboratories. A sample of the HFSRB-CCF for each type of specimen is available at the following website: www.doh.gov.ph

7.2 Accessioning

The laboratory must:

7.2.1 Provide a unique accession number upon entry of the specimen to the laboratory;
7.2.2 Inspect the specimen submitted and CCF to verify the integrity and identity of the specimen;
7.2.3 Examine the packaging for evidence of tampering in transit;
7.2.4 Compare the information on the sample bottles within the package with the information on the accompanying CCF; and
7.2.5 Document all discrepancies.

7.3 Security Measures

7.3.1 A laboratory must control access of unauthorized individual and ensure that no unauthorized individual can gain access to specimen, aliquots, or records.
7.3.2 All authorized visitors must be escorted at all times.
7.3.3 A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas.

www.doh.gov.ph
8.1 Techniques

8.1.1 Screening

8.1.1.1 Immunoassay

These methods are used for preliminary screening (i.e. initial screening), based on an antibody-antigen reaction. Small amounts of the drug and/or metabolite(s) may be detected. The following are examples of this technique:

(a) Enzyme immunoassay (EIA)
(b) Enzyme-multiplied immunoassay technique (EMIT)
(c) Fluorescence polarization
(d) Radioimmunoassay (RIA)

8.1.1.2 Chromatography

Separation of the mixture is the main outcome of the chromatographic method. In this process, a mixture of substances is separated in a stationary medium. The types of chromatographic processes are:

(a) Thin Layer Chromatography (TLC)
(b) Gas Chromatography (GC)
(c) Liquid Chromatography (e.g. HPLC)

8.1.2 Confirmatory

8.1.2.1 Hyphenated technique

Combination of two sophisticated technologies (e.g. GC-MS) or other such modern and acceptable techniques (e.g. LC-MS, GC-MS-MS or LC-MS-MS).

8.2 Test

8.2.1 Screening Laboratory

8.2.1.1 A laboratory that performs a validated test to differentiate negative specimen from a specimen that requires further testing for drugs and/or metabolite.

8.2.1.2 The method used may be:

(a) A registered testing kits approved by the DOH
(b) Instrumented screening method
8.2.1.3. A screening laboratory may conduct a repeat screening test on the same sample prior to the confirmatory test.

8.2.1.4 The screening laboratory must submit all samples with positive results to any DOH accredited confirmatory drug testing laboratory. Together with the sample, the following documents shall be submitted:
   (a) Accomplished Custody and Control Form
   (b) Initial Laboratory Report
   (c) Letter Request for Confirmatory Test

8.2.1.5 The release of the results will be dependent on the:
   (a) Availability of confirmatory laboratory
   (b) Distance of confirmatory laboratory from the Screening laboratory

8.2.1.6 The screening laboratory must keep specimen with a negative result for a minimum of 5 days upon receipt of result. In case the result is not retrieved by the Client/Donor/Subject the laboratory has the option to discard the specimen after 5 days.

8.2.2 Confirmatory Laboratory

8.2.2.1 A laboratory that performs a confirmatory analysis using validated analytical procedure by NRL of an aliquot of specimen submitted from a screening laboratory in order to identify and quantify the presence of a metabolite.

8.2.2.2 The procedure used must combine chromatographic separation and mass spectrometric identification in the same procedure (e.g., GC/MS, LC/MS, GC/MS/MS or LC/MS/MS).

8.2.2.3 All confirmatory laboratories must accept specimen tested positive from a screening laboratory with accompanying request for confirmatory testing and previous result of analysis.

8.2.2.4 Confirmatory laboratory must keep the remaining specimen tested positive. Only the results of the confirmatory test will be given to the screening laboratory.

8.2.2.5 The confirmatory laboratory must release results within three (3) to five (5) working days upon receipt of the specimen depending on workload and availability of equipment and supplies. For criminal case-related drug testing, the confirmatory result should be released 24 hours after submission of specimen. In case, the test cannot be done, notify the requesting party to refer to another confirmatory laboratory.
CHAPTER 9

URINE SPECIMEN VALIDITY TEST

A validity test is a test to determine the integrity of the specimen.

9.1 Validity procedures for unobserved urine collection to determine the integrity of the specimen.

9.1.1 Perform initial validity tests.

9.1.1.1 Urine physical examination in the following conditions:
   (a) Temperature
   (b) Abnormal physical appearance (e.g., color, odor, excessive foaming);
   (c) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g. non-recovery of standards, unusual response); or
   (d) Possible unidentified interfering substance or adulterant. The choice of additional validity tests is dependent on the observed indicators or characteristics as described in a (a) (b).

9.1.1.2 Urine specific gravity, pH and nitrites;
9.1.1.3 Urine creatinine concentration;
9.1.1.4 Validity test(s) for presence of oxidizing adulterants as needed.

9.1.2 Perform confirmatory validity tests using other procedures, instruments and/or methods on the same sample.

Notes:

i) All unobserved samples for validity testing shall be submitted to an accredited drug testing facility with at least secondary clinical laboratory capability.

ii) Validity tests for other types of specimen shall be incorporated for future reference.

9.2 Criteria for determining urine specimen

9.2.1 Invalid:
A urine specimen is invalid when:
9.2.1.1 Adulterated, substituted and diluted;
9.2.1.2 Improperly collected, handled and stored; and
9.2.1.3 Improperly documented

9.2.2 Adulterated:
9.2.2.1 The nitrite concentration is confirmed to be greater than or equal to 500µg/L;
9.2.2.2 The pH is less than 3 or greater than or equal to 11;
9.2.2.3 The specimen contains an exogenous substance (i.e., a substance which is not a normal constituents of urine); or
9.2.2.4 The specimen contains an endogenous substance at a concentration greater than what is considered a normal physiological concentration
9.2.3 Substituted:
A urine specimen is reported substituted for non-human urine specimen when both the initial and confirmatory creatinine tests and initial and confirmatory specific gravity tests have the following results:

9.2.3.1 The creatinine concentration is less than 442.0 µmol/L; and

9.2.3.2 Specific gravity is less than 1.002 or greater than or equal to 1.020.

9.2.4 Diluted:
A urine specimen is reported dilute when the initial or confirmatory tests have creatinine and specific gravity results of:

9.2.4.1 The creatinine concentration is less than 1768.0 µmol/L;

9.2.4.2 The specific gravity is less than 1.003; and

9.2.4.3 The creatinine and specific gravity results do not meet the criteria for a substituted or invalid result.

9.3 Procedures for conducting each validity test on a urine specimen

9.3.1 For creatinine concentration:

9.3.1.1 The creatinine concentration shall be measured to one decimal place on both the initial test and the confirmatory test;

9.3.1.2 The initial creatinine test shall have a calibrator at either 442.0 µmol/L or at 1768.0 µmol/L;

9.3.1.3 The initial creatinine test shall have a control in the range of 176.8 µmol/L to 353.6 µmol/L, a control in the range of 442.0 µmol/L to 1786.0 µmol/L, and a control in the range of 1856.4 µmol/L to 2210.0 µmol/L;

9.3.1.4 The confirmatory creatinine test (performed on that specimen with a creatinine concentration less than 442.0 µmol/L on the initial test) shall have a calibrator at 442.0 µmol/L or at 1768.0 µmol/L, a control in the range of 176.8 µmol/L to 353.6 µmol/L, and a control in the range of 530.4 µmol/L to 707.2 µmol/L.
9.3.2 For specific gravity:

9.3.2.1 The specific gravity shall be measured using a refractometer on both initial and confirmatory tests. The refractometer shall be capable of reading in increments of at least 0.001 or less.

9.3.2.2 The initial and confirmatory specific gravity tests shall have a calibrator at 1.000.

9.3.2.3 The initial and confirmatory specific gravity tests shall have the following controls:

(a) For the cutoff less than 1.002, one control at 1.001 and one control in the range of 1.002 to 1.010.

(b) For the cutoff greater than or equal to 1.020, one control greater than or equal to 1.020 but not greater than 1.025, and one control in the range of 1.015 to 1.020.

9.3.3 For pH:

9.3.3.1 Dipsticks, pH paper or spectrometric/colorimetric tests may be used for initial validity test.

9.3.3.2 A pH meter shall be used to perform confirmatory validity test.

9.3.3.3 The initial and confirmatory pH meter tests shall have the following controls:

(a) For the cutoff of less than 3, one control in the range of 2 to 2.9 and one control in the range of 3.1 to 4.

(b) For the cutoff of greater than or equal to 11, one control in the range of 10 to 10.9 and one control in the range of 11.1 to 12.

(c) Spectrometric/colorimetric initial pH tests shall have the following controls:
   (i) For the cutoff of less than 3, one control in the range of 2 to 2.9.
   (ii) For the cutoff of greater than or equal to 11, one control in the range of 11.1 to 12

9.3.4 For oxidizing adulterant tests:

9.3.4.1 At a maximum, the initial test(s) for oxidizing adulterants shall be capable of detecting nitrites, chromates, and halogens (e.g., bleach, iodine). The detection of these adulterants may be achieved by using either a general oxidizing adulterant test or by using specific test for each category of these adulterants. If an initial test for oxidizing adulterants simultaneously tests for all oxidizing adulterants, the assay shall be able to detect at least the activity equivalent to 20 mcg/mL of chromate (chromium VI) or 200mg/mL of nitrite
as an LOD. Each analytical run of specimen shall include a control without the compound of interest (i.e., accredited negative control) and at least one positive control with one of the compounds of interest at a concentration, which exhibits an oxidizing activity above the documented LOD of the procedure.

9.3.4.2 A confirmatory test for a specific oxidizing adulterant shall use a different analytical principle or chemical reaction than that used for the initial test unless a recognized reference method is used for both the initial and confirmatory tests. Each analytical run of specimen shall include a control without a compound of interest (i.e. accredited negative control) and a positive control with the compound of interest at a concentration above the documented LOD of the procedure.

9.3.5 For nitrite concentration

9.3.5.1 Dipsticks may only be used to determine if initial and confirmatory nitrite tests shall be performed.

9.3.5.2 A nitrite specific initial test shall have a calibrator at the cutoff concentration, a negative control (i.e., accredited negative urine), one control in the range of 200mcg/ml. to 500mcg/ml., and one control in the range of 500mcg/ml. to 625mcg/ml.

9.3.5.3 The confirmatory nitrite test shall have a calibrator at the cutoff concentration, a negative control (i.e., accredited negative urine), one control in the range of 200 mcg/ml to 500 mcg/ml., and one control in the range of 500 mcg/ml. to 625 mcg/ml.

9.3.6 For other validity tests (e.g., glutaraldehyde, surfactants):

9.3.6.1 Each analytical run of specimen shall include a control without the compound of interest (i.e., a negative control) and a positive control with the compound of interest at a concentration above the documented LOD of the procedure.

9.3.6.2 A confirmatory test for a specific adulterant shall use a different analytical principle or chemical reaction than that used for the initial test unless a recognized reference method is used for both the initial and confirmatory tests.

9.3.6.3 The initial and confirmatory tests for anionic surfactants shall be able to detect at least the activity equivalent to 100 mcg/ml. of dodecybenzene sulfonate.

Note: Deviations on the above numerical values may vary depending on the prevailing technology, procedure and reference materials used by the laboratory.