

SPECIMEN COLLECTION - TRANSPORTATION TO THE TESTING LABORATORY

1. COLLECTION OF SPECIMENS

a. **Collection Procedure.** This procedure will be under the direct control of the collection site personnel.

(1) The collector shall ensure that necessary supplies are available in sufficient quantity to complete scheduled collections. All unnecessary material at the site shall be removed and, thereafter, the collector shall have the site under direct observation.

(2) The urination area shall be partitioned off, if necessary (existing bathroom stall with door is acceptable).

(3) A bluing material shall be placed in the water of the toilet bowl or urinal and any accessible toilet tank for the purpose of preventing dilution of the sample with toilet water.

(4) The individual shall arrive at the collection site on time, as designated by the DPC (Drug Program Coordinator). If the individual fails to appear at the pre-designated time, the DPC will be notified by the collection site supervisor. Specific local instructions should be provided on who to contact when an individual fails to report. In such instances, the collector will note on the list of individuals scheduled for collections supplied by the DPC or Human Resources Management Officer, next to the name of the person who failed to report, the date and the notation, "Failed to appear."

(5) The collector must verify the identity of the individual to be tested. When an individual arrives at the collection site, the collector shall request the individual to present photo identification. If the individual does not have proper photo identification, the collector will contact the DPC or any other appropriate official, in accordance with locally established policy, who can positively identify the individual. If the individual's identity cannot be established, the collector shall not proceed with the collection.

(6) The individual shall be asked to remove unnecessary outer garments (coat, hat, gloves, etc.) and handbags that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(7) Once positive identification has occurred, the collector opens the collection kit and removes the contents in the individual's presence (hereafter, referred to as "donor"). Then the collector completes the following information on the chain of custody form:

(a) **NOTE: Split specimen procedures will be followed as described in this handbook.** Collection site personnel shall prepare two specimen bottles for collection (hereafter, referred to as Bottle A and Bottle B).

(b) Step 1A: Enter the facility name, address and station number of the donor.

(c) Step 1B: Enter the name of the MRO (Medical Review Officer) and the facility address where the MRO is employed.

(d) Step 1C: Enter the Donor's Social Security number.

(e) Step 1D: Place an "X" in the appropriate box (e.g., "Pre-employment, Random, etc.").

(f) Step 1E: Place an "X" next to "THC, Cocaine, PCP, Opiates, and Amphetamines."

(g) The chain of custody forms are sequentially numbered. They must be used in numerical order and must be strictly accounted for.

(8) The donor shall be instructed to wash and dry hands prior to urination. After washing hands, the donor shall remain in the presence of the collector and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

(9) The pre-sealed urine specimen Bottle A shall be given to the donor by the collector. The donor and the collector will inspect the specimen bottle in the presence of each other. If the collector notices that tampering or alteration of the sealed bottle has occurred, a new collection kit will be obtained.

(10) Unless the collector is instructed otherwise, or as specified in subparagraph 1a.21, when there is a reason to believe the donor may alter or substitute the specimen to be provided, the donor may provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The Chief, Pathology and Laboratory Medicine Service, shall review and concur in advance with any decision by a collector to obtain a specimen under the direct observation of a same gender individual based on a reason to believe that the donor may alter or substitute the specimen provided. The reason for collection under observation will be noted in Step 5 of the chain of custody form under the section for remarks. The remarks must be initialed by the Chief, Pathology and Laboratory Medicine Service, indicating concurrence.

(11) The seal under the cap of the specimen **Bottle A** will be removed by male donors who will be asked to urinate directly into the specimen bottle. Females will be given the wide mouth container for specimen collection. A specimen of at least 45 milliliters (mL) (approximately 2/3 of full specimen container) will be provided by both the male and female donor. The donor will be instructed not to flush the toilet.

(12) The collector will remain at the collection site but outside of the stall (or partition) until the urine specimen is collected by the donor and the specimen container is handed to the collector. The donor will hand the specimen container to the collector immediately after voiding.

(13) After the collector has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collector in completing the chain of custody form. Both the individual being tested and the collector shall keep the specimen in view at all times prior to its being sealed and labeled.

(14) The collector shall determine that at least 45 mL (milliliters) of urine is obtained from the donor. If at least 45 mL of urine is collected, skip subparagraph 15 through 16 and proceed with subparagraph 17 below.

(15) If the volume collected is less than 30 mL, the action taken will depend on the temperature of the specimen.

(a) If the temperature **is within** the acceptable range specified in subparagraph 18, the specimen **shall be discarded** and a second specimen shall be collected. The donor may be given a reasonable amount of water to drink (not more than 24 ounces of fluid, within a period of up to 2 hours), and then again attempt to provide a complete sample using a fresh collection container. The collector may use the same chain of custody form for the second specimen. The donor must remain within the area of the collection site during this time. The collector should note in Step 5 of the chain of custody form that the original specimen was discarded due to insufficient volume. If on the second attempt, the donor provides at least 30 mL but less than 45 mL, the donor forfeits the use of the split specimen procedure. If the donor fails for any reason to provide at least 30 mL of urine on the second attempt, after drinking at most 24 ounces of fluid, the insufficient specimen shall be discarded, testing shall be discontinued and the Chief, Human Resources Management Service or appropriate management official, shall be advised.

(b) If the temperature **is outside** the acceptable range specified in subparagraph 18, another specimen shall be collected under direct observation of a person of the same gender and **both specimens** shall be forwarded to the laboratory for testing. The donor may be given a reasonable amount of water to drink (not more than 24 ounces of fluid, within a period of up to 2 hours), to provide the second specimen. The collector must use a separate chain of custody form for both specimens. Each specimen shall be inspected in accordance with subparagraph 20 below. The temperature of both specimens shall be measured in accordance with subparagraph 18. If on the second attempt, the donor provides at least 30 mL but less than 45 mL, the donor forfeits the use of the split specimen procedure. If the donor fails for any reason to provide at least 30 mL of urine on the second attempt, after drinking at most 24 ounces of fluid, the insufficient specimen shall be sent to the laboratory with the original specimen, and the Chief, Human Resources Management Service or appropriate management official, shall be advised.

(16) If the volume collected is at least 30 mL but less than 45 mL, the action taken will depend on the temperature of the split specimen.

(a) If the temperature **is within** the acceptable range, all of the urine should be poured (females) or remain in Bottle A and sent to the laboratory along with the chain of custody form. The collector should provide an appropriate comment in Step 5 of the chain of custody form in the line provided for remarks indicating that the donor did not provide a sufficient volume for Bottle B. The donor forfeits the use of the split specimen collection procedure.

(b) If the temperature **is outside** the acceptable temperature range, another specimen shall be collected under direct observation of a person of the same gender and **both specimens** shall be forwarded to the laboratory for testing. The donor may be given a reasonable amount of water to drink (not more than 24 ounces of fluid, within a period of up to 2 hours), to provide the second specimen. The collector must use a separate chain of custody form for both specimens. If the donor fails to provide 45 mL for the split specimen, the donor forfeits the use of the split specimen procedure. If the donor fails for any reason to provide at least 30 mL of urine on the second attempt, after

drinking at most 24 ounces of fluid, the insufficient specimen shall be sent to the laboratory with the original specimen, and the Chief, Human Resources Management Service or appropriate management official, shall be advised.

NOTE: Under no circumstances is the collector permitted to collect and add or combine urine from two separate voids.

(17) After the specimen has been provided and submitted to the collector, the donor shall be allowed to wash hands.

(18) Within 4 minutes after urination, the collector will measure the temperature of the urine using the thermometer on collection Bottle A. The temperature is then recorded in Step 2 of the chain of custody form. In Step 2 of the chain of custody form, place an "X" in the appropriate block to indicate whether the temperature was within the acceptable range. If it was not, place an "X" in the "NO" block and record the actual temperature of the specimen. If the temperature is outside the range of 32 - 38° C/ 90 - 100°F, that is a reason to believe that the donor may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collector or same gender individual and both specimens shall be forwarded separately to the laboratory for testing.

(19) A donor may volunteer to have an oral temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range. If an oral temperature is taken, it should be recorded on the chain of custody form under Step 5 "Remarks."

(20) Immediately after the specimen is collected, the collector shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted under Step 5 "Remarks" of the chain of custody form. If it is apparent on visual inspection that the donor has adulterated the specimen (e.g., blue dye or other contaminants in the urine), the collector shall collect another specimen under direct observation in accordance with subparagraph 21 below.

(21) Whenever there is a reason to believe that a particular individual has altered or substituted the specimen provided, a second specimen shall be obtained as soon as possible under the direct observation of the same gender collector or individual selected by the Chief, Pathology and Laboratory Medicine Service, and will be recorded on a separate chain of custody form. Both the original specimen and the second observed specimen will be forwarded to the laboratory for testing. **All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.**

(22) After determining the specimen temperature, the collector, in the presence of the donor, shall retain 30 mL in Bottle A (or pour 30 mL into Bottle A for females) for the primary specimen and pour at least 15 mL into Bottle B for the split specimen.

(23) The collector shall ensure that the specimen bottle caps are securely screwed on.

(24) **NOTE: The collection kit contains two red serrated strips that should be placed over the Bottle tops prior to affixing the peel off labels from the form. The red strips should seal the bottles UNDER the peel off labels from the form. The red strips provide an added protection for the donor.** The collector shall place the gummed labels from the form securely across the top and down the sides of specimen Bottle A and Bottle B (directly over the red strips) in view of the donor. The collector shall date each label and instruct the donor to initial each label. Refusal to initial the labels shall be noted on the label by the collector.

(25) The collector shall instruct the donor to complete Copy 4 ("Medical Review Officer" copy) Step 4 of the chain of custody form. The donor shall indicate a daytime and evening phone number, date of birth and after reading the certification statement that the specimen identified as having been collected from the donor is in fact that specimen the donor provided, print his/her name with middle initial, sign, and date the form. If the donor refuses to complete/sign step 4 of the chain of custody form, the collector shall note this refusal in step 5 under "Remarks."

(26) The collector shall complete Step 5 of the chain of custody form, inserting the field facility name, address, collector's phone number, and indicate "yes" for split specimen collection. The collector (after noting any remarks regarding collection, if necessary) must print his/her name, sign and record the date and time of collection.

(27) The collector shall complete Step 6 of the chain of custody form. The collector will print and sign name and indicate the date the specimen was received and record any transfers of the specimen.

(28) The collector shall advise the donor of the opportunity to list any prescription and/or over-the-counter medications he or she may have recently taken on the back of the donor copy (copy 5) of the chain of custody form, but not on any other copy. This information will help the donor remember what medications he or she may have taken if a positive result is reported by the laboratory.

(29) Both bottles shall be shipped in a single shipping container, together with copies 1, 2, and 3 of the chain of custody form.

b. Collection Control

(1) While any part of the chain of custody procedures is being performed, it is essential that the urine specimen (Bottles A and B) and chain of custody documents be under the control of the collector. If the collector leaves the work station momentarily, the specimen and custody form shall be taken with the collector or shall be secured in a locker or locked refrigerator with access limited to collection site personnel only. After the collector returns

to the work station, the custody process will continue. If the collector is leaving for an extended period of time, the specimen shall be packaged for mailing before the collector leaves the site.

(2) To the maximum extent possible, collection site personnel shall keep the donor's specimen bottles within sight both before and after the specimen has been collected. After the specimen is collected, it shall be properly sealed and labeled. The approved chain of custody form is used to identify those individuals who come in contact with the sealed specimen bottles. The date and purpose shall be documented on this form, Step 6, each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

2. TRANSPORTATION TO THE DESIGNATED DRUG TEST LABORATORY

a. **Packaging.** Only the VA-approved specimen collection kits which include the collection bottles and shipping boxes will be used (see app. a of this Handbook). Steps 1 through 6 below will be completed in the donor's presence.

(1) The sealed specimen bottles will be placed in the leak proof specimen bag provided and placed in the gray foam insert in the bottom of the shipping box.

(2) Peel the Shipping Container Seal off the side of the chain of custody form and set aside. **NOTE: The collection kit contains a separate KIT SHIPPING SEAL. The KIT SHIPPING SEAL should be removed from the box and set aside with the Shipping Container Seal.**

(3) Then, separate copy number 1, "ORIGINAL," copy number 2, "2nd ORIGINAL" and copy number 3 "SPLIT SPECIMEN" of the chain of custody form, fold and place all three copies inside the leak proof specimen bag with the urine bottles. **NOTE:** If overnight delivery is required (e.g., DHL, express mail, etc.), complete appropriate mailing label (self-addressed to the MRO) and place the return label in the box.

(4) Close top of the box. **First, affix the KIT SHIPPING SEAL in the designated area. Then affix the Shipping Container Seal from the form directly OVER the KIT SHIPPING SEAL. This provides an added protection for the donor.** **NOTE:** The same person who last signed the chain of custody form (Step 6) must seal the box.

(5) The box will have a pre-printed mailing label affixed and addressed to the screening laboratory.

(6) On the Shipping Container Seal now sealing the shipping box containing the specimen, the collection site supervisor shall initial in the area designated "Collector's Initials" and enter the date the specimen was sealed in the container for shipment.

(7) Once the box has been sealed in the donor's presence, give the donor copy number 5 and release the individual as instructed by the DPC or Human Resources Management Officer. The donor must remain until the specimen is sealed in the shipping container.

(8) Copy number 4 of the chain of custody form is to be handcarried to the Medical Review Officer within 2 workdays so that the MRO may verify that all results have been received from the designated testing laboratory (see app. D of the Handbook for sample memorandum).

(9) Copy number 6 is to be retained by the collector in secured file.

(10) Copy number 7 is to be forwarded to the DPC with the original schedule of donors and kept in a secured file. For pre-employment testing, copy number 7 will sent to the Human Resources Management Officer.

b. **Delivery.** The sealed box containing the specimen, copies 1, 2 and 3 of the chain of custody form and the special mailing label if overnight delivery is required, will be delivered to the designated drug testing laboratory by carrying packaged specimen(s) to the mail room. Packages being sent via regular mail may be directly deposited into an official U.S. mail bag. Overnight deliveries must be given to the mailroom supervisor or designee for special handling. It is not necessary to use registered mail or return receipt mail when mailing specimens.

NOTE: The same person who sealed the box must place the specimen in the official U.S. mail bag or give it to the mailroom supervisor if overnight mailing is required. Specimens will be mailed from the collector's facility mail room only. If shipment by overnight courier is desired, see instructions in subparagraph 2.a.3. and subparagraph 2.c of this Handbook.

c. **Expedited Delivery to and from Testing Laboratory.** The screening laboratory will return the testing results by overnight delivery, but will do so only if a self-addressed label is included with each specimen. Failure to include the appropriate label (see subparagraph 2.a.3.) will result in return shipment by regular mail.

3. RECORDS. The Pathology and Laboratory Medicine Service that collects the specimens is only required to maintain copy 6 of the chain of custody form. Copy 6 should be stored in a secured file with access only by collection site personnel, the Chief of Pathology and Laboratory Medicine Service, MRO (Medical Review Official), Drug Program Coordinator, and facility Director.

NOTE: The Chief, Pathology and Laboratory Medicine Service is responsible for ensuring that all chain of custody forms are accounted for. Chain of custody forms have been sequentially numbered and must be used in that order. If, for any reason a form is voided, it should not be destroyed. Rather, write "VOIDED" across the form (sample in app. E of this Handbook). The Pathology and Laboratory Medicine Service should forward copy 4 of the "voided" chain of custody form to the MRO and retain all other copies in a secured file to ensure full accountability of all forms.

4. REPORTS OF DRUG TEST RESULTS. All results shall be reviewed by the MRO. The results will be reported directly to the MRO within an average of 5 working days after receipt of the urine sample by the designated testing laboratory (unless overnight delivery has been arranged). (The MRO may also receive a preliminary copy of the results via fax if the MRO has completed a form required by the testing laboratory (Minneapolis) indicating the MRO has a secured fax line.) The official results will be sent via overnight mail or regular mail. The laboratory that collected the specimens will not receive test results. Reports to the MRO will be in printed form only. Telephone reports are not permitted. A copy of the original chain of custody form, certified by the laboratory certifying official, will also be sent to the MRO. No positive results received by the MRO from the testing laboratory will be reported to VA administrative officials by the MRO unless verified positive by the MRO.

5. INFORMATION REGARDING TEST RESULTS FOR SPLIT SPECIMENS.

a. If the test of Bottle A is verified positive by the MRO, the MRO shall report the result to the Chief, Human Resources Management Service or appropriate management official. The MRO shall inform the donor of his/her right, in writing, to have Bottle B (split specimen) tested at another laboratory certified by the Department of Health and Human Services (HHS) for the presence of the drug(s) for which a positive result was obtained in the test of Bottle A. The employee may choose from a list of three pre-selected HHS-certified laboratories. The MRO will supply the list to the employee. The MRO must inform the donor of the requirement to make the request within 72 hours of the MRO informing the donor of the results. At that time, the donor may request, through the MRO, that Bottle B be tested. **Only the donor may make such a request.** The MRO shall honor such a request if it is made within 72 hours of the donor's having received notice that he or she tested positive. If such a request is made, the MRO will contact the VAMC Minneapolis laboratory, in writing, and request Bottle B, identified by specimen identification number, be sent to the HHS-certified laboratory the donor has selected. The result of this test (Bottle B) shall be transmitted to the MRO without regard to the cutoff levels used to test Bottle A.

b. Any action taken as a result of an MRO-verified positive drug test (e.g., removal from performing safety-sensitive duties) may proceed whether Bottle B is, or is not, tested.

c. If the result of the split specimen fails to reconfirm the verified positive result reported for the primary specimen (Bottle A), the MRO shall cancel the primary test result. The MRO shall report the cancellation and the reasons for it to the Human Resources Management Service or appropriate management official at the facility and the Drug Program Administrator, Office of Human Resources Management, VA Headquarters, 810 Vermont Avenue, NW, Washington, DC 20420.