

VA BLIND PERFORMANCE TEST PROCEDURES
Submission Instructions for VA Urine Collection Sites

In addition to collecting and transporting urine specimens of donors, collection site personnel will be responsible for submitting blind PT (performance test) samples to the designated drug testing laboratory. This requirement is in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs published by the Department of Health and Human Services.

The blind PT samples will be purchased from ElSohly Laboratories, Inc. The distribution of the samples may be limited to selected VA sites; therefore, it is important that collection site personnel who receive a shipment of blind PT samples adhere to the submission instructions in this appendix.

When submitted to the drug testing laboratory, the blind PT sample bottles, labels, and packaging must be identical to actual urine specimens collected from individuals. The credibility of the VA's drug detection program depends on absolute control and processing accuracy for blind PT samples. Compliance with the submission instructions is mandatory.

NOTE: ElSohly uses the terminology QC ("quality control") and "performance test" when referring to samples obtained from ElSohly. Since the Mandatory Guidelines for Federal Workplace Drug Testing Programs have designated the procedures as the blind performance test procedures, all VA references to the blind performance test samples and procedures will be consistent with the Mandatory Guidelines. For clarity reasons, the term "sample" will be used in VA submission instructions when referring to an ElSohly blind performance test sample; and the term "specimen" will be used when referring to donors' actual urine specimens.

1. LABORATORY COLLECTION SITE INSTRUCTIONS

a. **Reviewing the Blind PT Sample Shipment.** The ElSohly shipment of blind PT samples must be checked immediately upon receipt. An ElSohly Control Log will be enclosed for each set of samples. **NOTE: Separate Control Logs will be enclosed for positive and negative samples.** An example of the ElSohly Control Logs is provided in appendix G of this Handbook. Fictitious names and Social Security numbers will be provided by ElSohly and will appear on their control logs. **NOTE: Disregard the names on the control logs. Do not insert a name on the chain of custody form on Copy 4, Step 4. Insert the "ElSohly SSN #" on Copy 4, Step 4 in the space provided for the donor's printed name. Write "BLIND PT SAMPLE" in the space provided for the donor's signature. See sample in appendix H of this Handbook.**

b. **Split Specimen Samples.** The collector must follow the same procedures for preparing a split specimen sample as if it were an actual donor providing the specimen (i.e., use two collection bottles, Bottle A and Bottle B, pour at least 30 mL of urine into Bottle A and at least 15 mL of urine into Bottle B).

(1) Collection site personnel will compare the Social Security number on each ElSohly bottle with each Social Security number on the ElSohly Control Log. The numbers must match.

(2) Refrigerate the PT samples upon arrival and until they are submitted to the designated drug testing laboratory. If refrigeration is not possible, the samples must be stored in a cool place until submitted to the drug testing laboratory. In those instances, the ElSohly Control Logs shall be annotated that the samples were not refrigerated.

(3) All positive PT samples must be used within the time period designated on the ElSohly Sample Logs. Positive samples will be so labeled and must be sent out to the testing laboratory before their expiration date due to possible deterioration.

c. Packaging Elsohly Blind PT Samples. Elsohly PT samples must not be packaged until immediately prior to mailing the samples to the designated testing laboratory. VA specimen collection kits will be used to package blind performance test samples. When the samples are ready for packaging, it is important that each ElSohly blind PT sample is in bottles identical in size, color, and shape as the bottles in the VA Urine Specimen Collection Kit. This will ensure that the testing laboratory cannot identify the sample as a blind PT sample.

(1) After the ElSohly sample is received, the collector will use a VA collection kit to prepare the blind sample. The collector will pour at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B. After the bottles have been distributed the correct amount of urine, the following steps will be taken. (Collection site personnel will package only one sample at a time.)

(a) Complete the chain of custody form for the blind PT sample:

1. Step 1 - Insert the Employer name, address, I.D. number, MRO name and address, Donor Social Security number (SSN # provided by ElSohly), Reason for the test (select "Pre-employment") and Tests to be performed (select "THC, Cocaine, PCP, Opiates and Amphetamines").

2. Step 2 - Select "yes" for correct temperature range.

3. Step 3 - See paragraph 8. below.

4. Step 4 - See paragraph 7. below. Complete donor information.

5. Step 5 - Insert Collection facility name, address, phone, print Collector's name, collector signs, dates and records time of test. Do not list any remarks concerning urine. Answer "yes" to split specimen box.

6. Step 6 - Collector prints and signs name for receiving specimen, and assures any additional persons sign for release and/or receipt of specimens.

7. On copy 4, Step 4, insert the ElSohly social security number in the space provided for the donor's printed name. Insert "BLIND PT SAMPLE" in the space provided for the donor's signature. (See sample in app. H in this Handbook).

8. 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. Place the peel off labels from the side of the chain of custody form (copy 1) securely across the top and down the sides of specimen Bottles A and B (over the red strips). Do not initial labels at this time. The collection site supervisor will initial labels as described in paragraph 10.

9. Enter the Specimen Identification No. from the chain of custody form under the space provided for ACCESS# on the ElSohly Control Log in app. G of this Handbook.

10. The collection site supervisor will verify that the chain of custody form, the ElSohly Control Log, and the bottle labels have been completed in accordance with these instructions. It is important to verify the Specimen Identification Number and the fictitious social security number from both the ElSohly bottle and the ElSohly Control Log. Following the review, the supervisor will initial in the space marked "Donor Initials" and date both bottle labels. **NOTE: Date on bottle labels must match with date on the chain of custody form.** Also, the supervisor will initial Step 4 (copies 4 through 7) of the chain of custody form in the space provided for the donor's certification signature and ensure copies 1, 2, and 3 of the chain of custody form do not reveal that it is a blind sample.

d. **Packaging Samples.** The blind PT samples and chain of custody forms are now ready to be packaged and sent to the designated drug testing laboratory. The samples will be packaged in the same manner as actual donor's specimens. Packaging instructions are contained in appendix B, paragraph 2a of this Handbook.

e. **Submitting Samples to the Testing Laboratory.** The blind PT samples will be sent to the designated testing laboratory and mixed with shipments of bottles of regularly collected urine specimens. If urine specimens are not collected during the time period designated on the ElSohly Control Log, submit the PT samples on the Friday of that designated testing week. Submit all PT samples and annotate on the ElSohly Control Log that no urine specimens were collected for drug testing during that designated submission time period. Check all packages to ensure that they are identical to packages containing actual donors' urine specimens (if, applicable).

(1) Note by the ACCESS# on the ElSohly Control Logs the date each sample was shipped from the facility to the designated Drug Testing Laboratory.

(2) After the last blind PT sample in each set is submitted, complete and return a copy of the ElSohly Control Logs to ElSohly using the mailing label enclosed with the blind PT samples. The collection site supervisor will sign the completed form. A copy of the completed ElSohly Control Log will be retained by the collection laboratory.

f. **Forwarding Forms to Medical Review Officer.** Collection site personnel will advise the Medical Review Officer when blind PT samples are submitted to the designated testing laboratory. The facility Chief of Pathology and Laboratory Medicine Service will provide the Medical Review Officer with copy

4 of the chain of custody form for each blind PT sample, just as would be provided for each specimen sent to the designated testing laboratory and a copy of the ElSohly Control Logs. (See sample memorandum in Appendix D of this Handbook.) Next to the Specimen Identification Number on the memorandum, the laboratory will note "Blind PT Sample." **NOTE:** Collection site personnel will forward an ElSohly mailing label, if available, to the MRO (Medical Review Officer) for the MRO's use in submitting test results to ElSohly.

2. RECORDS

Copy 7 of the chain of custody form will be forwarded to the Drug Program Coordinator. Copy 6 of the form will be retained by the collecting laboratory with the donor copy (copy 5). Copies of completed ElSohly Control Logs will be kept with the laboratory copies of the chain of custody forms.

3. MEDICAL REVIEW OFFICER BLIND PT INSTRUCTIONS

When the VAMC Minneapolis laboratory provides the test results on any ElSohly samples, the MRO must forward a copy of the ElSohly Control Logs indicating the results to:

ElSohly Laboratories, Inc.
5 Industrial Park Drive
Oxford, MS 38644