

transferring the specimen to the laboratory,

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (*e.g.*, standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

[65 FR 79526, Dec. 19, 2000, as amended at 71 FR 49384, Aug. 23, 2006]

### Subpart F—Drug Testing Laboratories

#### § 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

#### § 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) You are authorized to receive only Copy 1 of the CCF. You are not authorized to receive other copies of the CCF or any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

(c) You must inspect each specimen and CCF for the following “fatal flaws:”

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(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(3) The collector's printed name *and* signature are omitted from the CCF; and

(4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with § 40.97(a)(3).

(e) You must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of § 40.205(b)(1).

(3) If the flaw is not corrected, report the result as rejected for testing in accordance with § 40.97(a)(3).

(f) If you determine that the specimen temperature was not checked and the "Remarks" line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of § 40.208.

(1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.

(2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with § 40.97(a).

(g) If you determine that a CCF that fails to meet the requirements of § 40.45(a) (e.g., a non-Federal form or an expired Federal form was used for the collection), you must attempt to correct the use of the improper form by

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following the procedures of § 40.205(b)(2).

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.

(2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with § 40.97(a)(3).

(h) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (*i.e.*, Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the "A" and write "B," then initial and date the change. A corresponding change shall be made to the other bottle by marking through the "B" and writing "A," and initialing and dating the change.

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(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; 75 FR 59107, Sept. 27, 2010]

### § 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not

test “DOT specimens” for any other drugs.

- (a) Marijuana metabolites.
- (b) Cocaine metabolites.
- (c) Amphetamines.
- (d) Opiate metabolites.
- (e) Phencyclidine (PCP).

### § 40.87 What are the cutoff concentrations for drug tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff concentration	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites .....	50 ng/mL .....	THCA <sup>1</sup> .....	15 ng/mL.
Cocaine metabolites .....	150 ng/mL .....	Benzoyllecgonine .....	100 ng/mL.
Opiate metabolites			
Codeine/Morphine <sup>2</sup> .....	2000 ng/mL .....	Codeine .....	2000 ng/mL.
		Morphine .....	2000 ng/mL.
6-Acetylmorphine .....	10 ng/mL .....	6-Acetylmorphine .....	10 ng/mL.
Phencyclidine .....	25 ng/mL .....	Phencyclidine .....	25 ng/mL.
Amphetamines <sup>3</sup>			
AMP/MAMP <sup>4</sup> .....	500 ng/mL .....	Amphetamine .....	250 ng/mL.
		Methamphetamine <sup>5</sup> .....	250 ng/mL.
MDMA <sup>6</sup> .....	500 ng/mL .....	MDMA .....	250 ng/mL.
		MDA <sup>7</sup> .....	250 ng/mL.
		MDEA <sup>8</sup> .....	250 ng/mL.

<sup>1</sup> Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

<sup>2</sup> Morphine is the target analyte for codeine/morphine testing.

<sup>3</sup> Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

<sup>4</sup> Methamphetamine is the target analyte for amphetamine/methamphetamine testing.

<sup>5</sup> To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

<sup>6</sup> Methylenedioxymethamphetamine (MDMA).

<sup>7</sup> Methylenedioxyamphetamine (MDA).

<sup>8</sup> Methylenedioxyethylamphetamine (MDEA).

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 49862, Aug. 16, 2010; 77 FR 26473, May 4, 2012]

### § 40.89 What is validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(b) As a laboratory, you must conduct validity testing.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 73 FR 35970, June 25, 2008]