

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

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1. The authority citation for 49 CFR Part 40 continues to read as follows:

Authority: 40 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

what basis does the MRO verify test results for 6-AM?

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2. § 40.3 is amended as follows:

A. Revise the section heading.

B. Revise the definitions of Adulterated specimen, Confirmatory drug test, Initial drug test (also known as a Screening drug test), Invalid drug test, Laboratory, and Limit of detection (LOD).

C. Add in alphabetical order definitions of Initial specimen validity test, Limit of Quantitation, Negative result, Positive result, Reconfirmed, Rejected for testing, and Split specimen collection.

D. Remove the definition of Initial validity test.

The revisions and additions read as follows:

§ 40.3 What do the terms used in this part mean?

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Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

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Confirmatory drug test. A second analytical procedure performed on a different aliquot of

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the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

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Initial drug test (also known as a “Screening drug test”). The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial specimen validity test. The first test used to determine if a urine specimen is adulterated, diluted, substituted, or invalid.

Invalid drug test. The result reported by an HHS-certified laboratory in accordance with the criteria established by HHS Mandatory Guidelines when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

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Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards of Subpart C of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

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Limit of Detection (LOD). The lowest concentration at which a measurand can be identified, but (for quantitative assays) the concentration cannot be accurately calculated.

Limit of Quantitation. For quantitative assays, the lowest concentration at which the identity and concentration of the measurand can be accurately established.

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Negative result. The result reported by an HHS-certified laboratory to an MRO when a

specimen contains no drug or the concentration of the drug is less than the cutoff concentration for the drug or drug class and the specimen is a valid specimen.

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Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentrations.

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Reconfirmed. The result reported for a split specimen when the second laboratory is able to corroborate the original result reported for the primary specimen.

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Rejected for testing. The result reported by an HHS-certified laboratory when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

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Split specimen collection. A collection in which the urine collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

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3. In §40. 87, the section heading and paragraph (a) are revised, and paragraph (e) is added, to read as follows:

§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 THCA¹ 15 ng/mL

Cocaine metabolites 150 ng/mL Benzoyllecgonine 100 ng/mL

Opiate metabolites

Codeine/Morphine² 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

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Amphetamines³

AMP/MAMP⁴ 500 ng/mL Amphetamine 250 ng/mL

Methamphetamines⁵ 250 ng/mL

MDMA⁶ 500 ng/mL MDMA 250 ng/mL

MDA⁷ 250 ng/mL

MDEA⁸ 250 ng/mL

¹Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA)

²Morphine is the target analyte for codeine/morphine testing

³Either 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

4Methamphetamine is the target analyte for amphetamine/methamphetamine testing
5To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL

6Methylenedioxymethamphetamine (MDMA)

7Methylenedioxyamphetamine (MDA)

8Methylenedioxyethylamphetamine (MDEA)

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(e) On a 6-AM confirmed positive result:

(1) When a 6-AM confirmed positive result is reported and morphine for that specimen is not reported at or above the 2000 per ng/mL confirmed positive cutoff, you must confer with the MRO to determine if there was confirmed morphine below 2000 ng/mL.

(2) If morphine was not confirmed below 2000 ng/mL, you and the MRO must determine whether further testing is needed to quantify the amount of morphine concentration present.

(3) If you find no detectable morphine at LOD upon further testing, you must report that fact to ODAPC immediately.

4. In § 40.97, paragraph (g) is added to read as follows:

§ 40.97 What do laboratories report and how do they report it?

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(g) If you confirm 6-AM and find no detectable morphine at LOD upon further testing, you must report that fact to ODAPC immediately.

5. In § 40.121, paragraph (d) is revised to read as follows:

§ 40.121 Who is qualified to act as an MRO?

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(d) **Requalification Training.** During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c)(2) of this section or have successfully completed the required continuing education requirements which were mandatory prior to October 1, 2010, you must complete requalification training.

(1) This requalification training must meet the requirements of the qualification training under paragraph (c)(1) of this section.

(2) Following your completion of requalification training, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

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6. § 40.139 is revised to read as follows:

§ 40.139 On what basis does the MRO verify test results for codeine and morphine?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive morphine or codeine test result:

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(a) In the absence of 6-AM, if the laboratory detects the presence of either morphine or codeine at 15,000 ng/mL or above, you must verify the test result positive unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (e.g., poppy seeds) must not be considered a legitimate medical explanation for the employee having

morphine or codeine at these concentrations.

(b) For all other opiate positive results, you must verify a confirmed positive test result for opiates only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (i.e., morphine, heroin, or codeine).

(1) As an MRO, it is your responsibility to use your best professional and ethical judgment and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgment include, but are not limited to, the following:

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

(iv) Use of a medication from a foreign country. See § 40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (b)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

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(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (b)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for opiates, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you do not have grounds for verifying the test positive. The admission must be for the substance that was found).

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in paragraph (b) of this section. If you cannot make this determination (e.g., there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

7. A new § 40.140 is added to read as follows:

§ 40.140 On what basis does the MRO verify test results for 6-acetylmorphine (6-AM)?

As the MRO, you must proceed as follows when you receive a laboratory confirmed 6-AM test result:

(a) If the laboratory confirms the presence of 6-AM in the specimen and there is also any level of quantitation of morphine, you must verify the test result positive.

(b) When a laboratory 6-AM confirmed positive result is reported and morphine for that specimen is not reported at or above the 2000 per ng/mL confirmed positive cutoff, you must confer with the laboratory to determine if there was confirmed morphine below 2000 ng/mL.

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(1) If there was confirmed morphine below 2000 ng/mL, you must verify the test result positive.

(2) If morphine was not confirmed below 2000 ng/mL, you and the laboratory must determine whether further testing is needed to quantify the amount of morphine present.

(c) If a laboratory finds detectable morphine at its LOD upon further testing, you must

verify the test result positive.

(d) If a laboratory finds no detectable morphine at its LOD upon further testing, you and the laboratory must report that fact to the ODAPC immediately. Following your discussion with ODAPC, you will make a verified result determination.

8. In § 40.151, paragraph (g) is revised to read as follows:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

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(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6-AM, MDMA, MDA, or MDEA in a specimen.

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9. In § 40.159, paragraph (a)(6) is added to read as follows:

§ 40.159 What does the MRO do when a drug test is invalid?

(a) * * *

(6) When the test result is invalid because pH is greater than or equal to 9.0 but less than or equal to 9.5 and the employee has no other medical explanation for the pH, you should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.

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(i) You are authorized to consider the temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory, and the length of time between the specimen collection and arrival at the laboratory.

(ii) You may talk with the collection site and laboratory to discuss time and temperature issues, including any pertinent information regarding specimen storage.

(iii) If you determine that time and temperature account for the pH value, you must cancel the test and take no further action, as provided at paragraph (a)(4) of this section.

(iv) If you determine that time and temperature fail to account for the pH value, you must cancel the test and direct another collection under direct observation, as provided at paragraph (a)(5) of this section.

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10. In § 40.163, paragraph (h) is added to read as follows:

§ 40.163 How does the MRO report drug test results?

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(h) You must maintain reports and records related to negatives and cancelled results for one year; you must maintain reports and records related to positives and refusals for five years, unless otherwise specified by applicable DOT agency regulations.

11. Appendix B to part 40 is revised to read as follows:

Appendix B to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)

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Laboratory Identification: (name and address)

Employer Identification: (name; may include Billing Code or ID code)

C/TPA Identification: (where applicable; name and address)

1. Specimen Results Reported (total number)

By Test Reason:

(a) Pre-employment (number)

- (b) Post-Accident (number)
- (c) Random (number)
- (d) Reasonable Suspicion/Cause (number)
- (e) Return-to-Duty (number)
- (f) Follow-up (number)
- (g) Type of Test Not Noted on CCF (number)
- 2. Specimens Reported
 - (a) Negative (number)
 - (b) Negative and Dilute (number)
- 3. Specimens Reported as Rejected for Testing (total number)
By Reason
 - (a) Fatal flaw (number)
 - (b) Uncorrected Flaw (number)

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- 4. Specimens Reported as Positive (total number) By Drug
 - (a) Marijuana Metabolite (number)
 - (b) Cocaine Metabolite (number)
 - (c) Opiates (number)
 - (1) Codeine (number)
 - (2) Morphine (number)
 - (3) 6-AM (number)
 - (d) Phencyclidine (number)
 - (e) Amphetamines (number)
 - (1) Amphetamine (number)
 - (2) Methamphetamine (number)
 - (3) MDMA (number)
 - (4) MDA (number)
 - (5) MDEA (number)
- 5. Adulterated (number)
- 6. Substituted (number)
- 7. Invalid Result (number)
- 12. Appendix C to part 40 is revised to read as follows:

Appendix C to Part 40 - DOT Drug Testing Semi-Annual Laboratory Report to DOT

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Mail, fax, or email to:

U.S. Department of Transportation
Office of Drug and Alcohol Policy and Compliance
W62-300
1200 New Jersey Avenue, S.E.
Washington, DC 20590
Fax: (202) 366-3897
Email: ODAPCWebMail@dot.gov

The following items are required on each report:

Reporting Period: (inclusive dates)

Laboratory Identification: (name and address)

- 1. DOT Specimen Results Reported (total number)

2. Negative Results Reported (total number)

Negative (number)

Negative-Dilute (number)

3. Rejected for Testing Results Reported (total number)

By Reason

(a) Fatal flaw (number)

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(b) Uncorrected Flaw (number)

4. Positive Results Reported (total number)

By Drug

(a) Marijuana Metabolite (number)

(b) Cocaine Metabolite (number)

(c) Opiates (number)

(1) Codeine (number)

(2) Morphine (number)

(3) 6-AM (number)

(d) Phencyclidine (number)

(e) Amphetamines (number)

(1) Amphetamine (number)

(2) Methamphetamine (number)

(3) MDMA (number)

(4) MDA (number)

(5) MDEA (number)

5. Adulterated Results Reported (total number)

By Reason (number)

6. Substituted Results Reported (total number)

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7. Invalid Results Reported (total number)

By Reason (number)

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