

TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS

Initial test analyte	Initial test cutoff <sup>1</sup>	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC) <sup>2</sup>	4 ng/mL <sup>3</sup>	THC	2 ng/mL.
Cocaine/Benzoyllecgonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoyllecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL <sup>3</sup>	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.
MDMA <sup>4</sup> /MDA <sup>5</sup>	50 ng/mL	MDMA	25 ng/mL.
		MDA	25 ng/mL.

<sup>1</sup> For grouped analytes (*i.e.*, two or more analytes that are in the same drug class and have the same initial test cutoff): *Immunoassay*: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

*Alternate technology*: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.*, with concentrations equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

<sup>2</sup> An immunoassay must be calibrated with the target analyte.

<sup>3</sup> *Alternate technology (THC and 6-AM)*: The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.*, 2 ng/mL for THC, 2 ng/mL for 6-AM).

<sup>4</sup> Methylendioxyamphetamine (MDMA).

<sup>5</sup> Methylendioxyamphetamine (MDA).

[88 FR 27643, May 2, 2023]

#### § 40.92 What is oral fluid 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 oral fluid. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the oral fluid, if the oral fluid was altered.

(b) If a specimen exhibits abnormal characteristics (*e.g.*, unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.*, non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then you may conduct validity testing.

(c) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS-certified laboratory would be useful in being able to report a positive or adulterated test result.

[88 FR 27643, May 2, 2023]

#### § 40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

As a laboratory, if you conduct validity testing under § 40.92, you must conduct it in accordance with the requirements of this section.

(a) You may test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(b) You must follow the applicable HHS requirements for any additional validity testing.

[88 FR 27643, May 2, 2023]

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

(a) As a laboratory, when reporting a result of any kind, you must report the specimen type.

(b) You must also report the results for each primary specimen, which will fall into one of the following three categories. As a laboratory, you must report the actual results (and not the categories):

(1) *Category 1: Negative results*. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as applicable:

(i) Negative, or

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(ii) For urine only, negative-dilute, with numerical values for creatinine and specific gravity.

(2) *Category 2: Non-negative results.* As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as applicable:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);

(iii) For urine only, positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iv) For urine only, substituted, with confirmatory test values for creatinine and specific gravity; or

(v) For urine only, invalid result, with remark(s). Laboratories will report actual values for pH results.

(vi) For oral fluid only, invalid result, with remark(s). Laboratories must report numerical values of the specimen validity test results that support a specimen reported as invalid.

(3) *Category 3: Rejected for testing.* As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(c) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.*, a C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.*, computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

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(E) SSN or Employee ID from Step 1C of the CCF, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) For oral fluid only, collection device expiration date;

(J) Date received at the laboratory;

(K) Date certifying scientist released the results;

(L) Certifying scientist's name;

(M) Results (*e.g.*, positive, adulterated) as listed in paragraph (b) of this section; and

(N) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report must not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage (*e.g.*, see § 40.351).

(2) Non-negative and Rejected for Testing results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (c)(1)(i) and (ii) of this section.

(d) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax or other electronic means, the electronic communication must be accessible only to authorized individuals.

(e) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(f)(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute urine test result, without a request from the MRO.

(g) You must provide quantitative values for confirmed positive morphine and/or codeine urine results at or below 15,000 ng/mL, and for confirmed positive morphine or codeine oral fluid results at or below 150 ng/mL.

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**§ 40.101 What relationship may a laboratory have with an MRO?**

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an

MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

**§ 40.107 Who may inspect laboratories?**

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

**§ 40.109 What documentation must the laboratory keep, and for how long?**

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.*, for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

**§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?**

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in appendix D of this part with respect to each specimen type for which you conduct tests to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.