TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC) [2]	4 ng/mL [3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoylecgonine	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 [3]	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 [4]/MDA [5]	50 ng/mL	MDMA	25 ng/mL.
		MDA	25 ng/mL.

[1] 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.
[2] An immunoassay must be calibrated with the target analyte.
[3] *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).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (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