2023 Oral Fluid Guidelines
Summary of Major Changes to 2019 Oral Fluid Guidelines

Publish a separate FRN annually with drug testing panel, biomarker testing panel, and required nomenclature- *Sections 1.5, 3.1, 3.4, and 3.5*

1. Added definitions for Biomarker Testing Panel and Drug Testing Panel – *Section 1.5*
2. Revised definition for Cutoff to include biomarker concentration in the e.g. – *Section 1.5*
3. Revised definition for Invalid Result to include both adulterated and substituted as results that may be determined for OF – *Section 1.5*
4. Revised items a and b to reference drug testing panel; added new item d to address biomarker testing panel– *Section 3.1*
5. Revised item c to remove albumin and IgG as examples of biomarker tests; put general wording about other tests that could be used to identify specimens that are not valid for testing – *Section 3.1*
6. Added semi-solid characteristics as example of abnormal specimen characteristic– *Section 3.1*
7. Revised Section 3.4 header wording; stated that OFMG Section 3.4 table will be in effect until panel is published in separate FRN; and described annual FRN that will include authorized drugs, analytes, and cutoffs; authorized biomarkers, analytes, and cutoffs; and HHS-specified nomenclature (i.e., analyte names and abbreviations) for laboratory and MRO reports - *Section 3.4*
8. Revised examples of tests to be performed upon MRO request in Section 3.5: left "specimen validity tests"; removed "tetrahydrocannabivarin" – inappropriate example for oral fluid - *Section 3.5. Described in preamble under header Biomarker testing panel*: SAMHSA must approve biomarker analytes and cutoffs and NLCP must review validation records before a laboratory implements a biomarker test.

Report Substituted (not Invalid) based on biomarker testing - *Sections 1.5, 3.7, 3.9, 11.15, 11.17, 14.4, and 14.6*

1. Included Substituted Specimen definition; added reference to Section 3.7 of the Urine Mandatory Guidelines for creatinine and specific gravity criteria to report a urine specimen as substituted - *Section 1.5*
2. Revised Adulterated Specimen definition to remove "endogenous substance" and to state a "normal constituent (e.g., nitrite in urine)" - *Section 1.5*
3. Revised criteria to report a specimen as invalid: edited item 3.8(e) and 11.17(g) to be a placeholder for future specimen validity tests and removed criteria for biomarkers– *Section 3.8, Section 11.17*
4. Added new Section 3.7 with criteria for reporting a specimen as substituted – *Section 3.7*
5. Revised to require same general analytical and QC requirements for substituted as for invalid and adulterated specimens – *Section 11.15*
6. Added criteria to report a specimen as adulterated (item d) and as substituted (item e)– *Section 11.17*
7. Added new Section 14.4 to address how a laboratory tests a split specimen when the primary specimen was substituted - *Section 14.4*
8. Included MRO actions for a split that failed to reconfirm some or all positive/adulterated results and was substituted, and for a split that failed to reconfirm substitution– *Section 14.6*

9. Inserted new item k: MRO cancels test and directs observed recollection when B specimen fails to reconfirm adulteration or substitution AND is invalid – *Section 14.6(k)*

Require MRO semiannual summary reports to SAMHSA - *New Section 13.11*

1. Added section with requirements for MRO semiannual summary reports (January and July) of laboratory-reported positives that were verified as negative

Requirements for a federal agency regarding use of an MRO – *New Section 13.12*

1. Added section with federal agency's responsibilities for an MRO based on MRO requirements.

MRO verification of positive codeine/morphine specimens- *Section 13.5*

1. For positive specimens with codeine/morphine less than 150 ng/mL and no legitimate medical explanation: removed requirement for clinical evidence of illegal use in addition to drug test result - *Section 13.5(c)(3)(i)* (MRO reports such specimens as negative.)
2. For a positive specimen with codeine/morphine less than 150 ng/mL and no legitimate medical explanation: deleted statement re reporting positive if 6-AM is present - *Section13.5(d)(3)(i)*

Apply same "refusal to test" criteria for all donors – *Sections 1.7, 1.8, 8.3*

1. Removed allowance for pre-employment drug test donors: collector will report a refusal to test when any donor fails to appear within a reasonable time established by the federal agency, or leaves before the collection is completed - *Sections 1.7 and 1.8*
2. Added that collector informs donor that failure to follow instructions to remain at the collection site (in area designated by collector) until collection is complete will be reported as a refusal to test – *Section 8.3(h)(4)*

Collection Devices - *Sections 7.2 and 15.1*

1. Revised item b to clarify that a device may have one or two collection tubes - *Section 7.2*
2. Added new item (b)(2) for tubes to be sufficiently transparent to enable visual inspection of contents without opening the tube- *Section 7.2*
3. Added new item (b)(3) to require manufacturers to include the device lot expiration date on each tube- *Section 7.2*
4. Added new item c requiring laboratories to reject specimens collected using an expired device (i.e., expiration date precedes collection date), unless B can be redesignated. *Section 15.1*

Additional edits were made based on the above major changes, as well as wording edits for clarity and edits for consistency with the 2023 Federal CCF, HHS Oral Fluid Specimen Collection Handbook, and HHS Medical Review Officer Guidance Manual.

Oral Fluid Collection – additional edits

Section 8.4:

1. Added new item a requiring the donor to wash their hands under collector's observation and reporting failure to cooperate as a refusal to test
2. Reworded item b to address use of one or two devices for the split collection, including reference to section 8.8(a) for device types that may be used
3. Specified in item b.1 that the collector opens the collection device package
4. Added "an attempt to prevent the device from collecting sufficient oral fluid" as an example of donor conduct that constitutes a refusal to test to item d

Section 8.5:

1. Added item (a)(3) to require the collector to inspect the collected specimen for abnormal physical appearance

Medical Review Officer Review/Verification- additional edits

Section 13.5:

1. Added in item (c)(2) that, for specimens with multiple results, the MRO takes action for an invalid result when the specimen's other results (positive, adulterated, or substituted) are verified negative based on a legitimate medical explanation.
2. Added new item (d)(1) stating that the MRO reports a positive result when the donor admits unauthorized use of the drug(s) that caused the positive test result. Added that the MRO must document the donor's admission of unauthorized use in the MRO records and the report to the federal agency.
3. Revised item (c)(2)(ii) re ingestion of food products containing a drug to apply to any positive drug test results, not only positive marijuana results; added wording to include the exceptions for positive codeine and morphine.
4. Added item (c)(2)(iii) stating that a physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate explanation for a positive drug test result.
5. Revised (e)(2)(ii) re when a recollection after invalid is still invalid, MRO cancels test and recommends recollection of different specimen type. Added: if agency does not authorize another specimen type, MRO consults with agency to arrange clinical evaluation to determine if there is a valid medical reason for the invalid result.