2023 Urine Guidelines
Summary of Major Changes to 2017 Urine Guidelines

Raised morphine confirmatory cutoff to 4,000 ng/mL- *Section 3.4*

1. Raised morphine confirmatory cutoff from 2,000 ng/mL to 4,000 ng/mL in analytes/cutoffs table to rule out possibility of positives due to poppy seed ingestion.

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 items a and b to reference drug testing panel; added new item d to address biomarker testing panel– *Section 3.1*
4. Revised Section 3.4 header wording; stated that UrMG 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 IITF, laboratory, and MRO reports - *Section 3.4*
5. Removed example allowing laboratories to test a specimen for a biomarker upon MRO request - *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, 11.19, 14.4, and 14.6*

1. Revised Substituted Specimen definition to include “absence of a biomarker or biomarker concentration outside that established for a human specimen” and 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 3.9(m) to be a placeholder for future specimen validity tests and removed criteria for biomarkers– *Section 3.9*
4. Revised criteria to report a specimen as substituted – *Sections 3.7, 11.19,14.4(a)*
5. Revised MRO actions for a split that failed to reconfirm some or all positive/adulterated results and was substituted – *14.6(c)*
6. Inserted new item k: MRO cancels test and directs observed recollection when B specimen fails to reconfirm adulteration or substitution AND is invalid *– 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 codeine/morphine specimens: removed requirement for MRO to determine clinical evidence of illegal use (in addition to the test result) to report positive – *Section 13.5(d)(3)(i)* (MRO reports such specimens as negative unless donor admits use)
2. Removed codeine/morphine decision point (15,000 ng/mL) to rule out poppy seeds as reason for positive (positive/negative based on 2000 ng/mL codeine cutoff; 4000 ng/mL morphine cutoff) - Described in preamble under header *Medical Review Officer (MRO) verification of codeine and morphine test results* - *Sections 13.5(c)(2)(i), 13.5(d)(3)(i), 13.5(d)(3)(ii),*

Apply same "refusal to test" criteria for all donors - *Sections 1.7, 1.8, 8.5*

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 8.5(a)*

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 Urine Specimen Collection Handbook, and HHS Medical Review Officer Guidance Manual.

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 items (d)(2)(i) and (ii) to apply to any positive urine drug test results, not only positive marijuana results: item i re passive exposure, item ii re ingestion of food products containing a drug.
4. Added item (d)(2)(iii) stating that a physician's authorization or medical recommendation for a Schedule I controlled substance is not an acceptable medical explanation for a positive drug test.
5. Revised (f)(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.