

## **2024 Medical Review Officer (MRO) Case Studies – Oral Fluid**

**These case studies provide examples to supplement the Department of Health and Human Services (HHS) MRO Guidance Manual, February 1, 2024.**

**The manual and case studies apply to federal agency drug testing programs that come under Executive Order 12564 dated September 15, 1986, section 503 of Public Law 100-71, 5 U.S.C. section 7301 note dated July 11, 1987, and the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (88 FR 70814) dated October 12, 2023 (effective October 10, 2023).**

**The manual and case studies do not apply to specimens submitted for testing under Department of Transportation (DOT) Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40).**

**The MRO Case Studies will be updated as needed to reflect new information. The current version is available on the Drug Testing page under *Medical Review Officer (MRO) Resources* on the Substance Abuse and Mental Health Services Administration (SAMHSA) website:**

**<https://www.samhsa.gov/workplace>**

## Table of Contents for Oral Fluid Case Studies

<u>Case #1 Laboratory Reported Result: Positive for Marijuana (<math>\Delta</math>9-THC) – 11 ng/mL</u>	<u>4</u>
<u>Case #2 Laboratory Reported Result: Positive for Morphine – 135 ng/mL</u>	<u>5</u>
<u>Case #3 Laboratory Reported Result: Positive for Codeine – 143 ng/mL</u>	<u>6</u>
<u>Case #4 Laboratory Reported Result: Positive for Codeine – 340 ng/mL</u>	<u>7</u>
<u>Case #5 Laboratory Reported Result: Positive for Methamphetamine – 192 ng/mL</u>	<u>8</u>
<u>Case #6 Laboratory Reported Result: Positive for Cocaine – 10 ng/mL and Cocaine Metabolite (Benzoylecgonine [BZE]) – 78 ng/mL</u>	<u>9</u>
<u>Case #7 Laboratory Reported Result: Positive for Morphine – 35 ng/mL</u>	<u>10</u>
<u>Case #8 Laboratory Reported Result: Positive for Methamphetamine – 250 ng/mL and Amphetamine - 30 ng/mL</u>	<u>11</u>
<u>Case #9 Laboratory Reported Result: Positive for Methamphetamine – 213 ng/mL</u>	<u>13</u>
<u>Case #10 Laboratory Reported Result: Invalid Result – Immunoassay Interference</u>	<u>15</u>
<u>Case #11 Laboratory Reported Result: Adulterated (Specify Adulterant) Present = (confirmatory test value) and Invalid Result – Tube A and Tube B – Different Physical Appearance</u>	<u>16</u>
<u>Case #12 Laboratory Reported Result: Positive for Marijuana (<math>\Delta</math>9-THC) – 2 ng/mL, Cocaine - 21 ng/mL, and Cocaine Metabolite (BZE) – 35 ng/mL</u>	<u>17</u>
<u>Case #13 Laboratory Reported Result: Rejected for Testing – Fatal Flaw: Tube A label/seal broken</u>	<u>18</u>
<u>Case #14 First Laboratory Reported Result: Negative and Invalid – Tube A and Tube B – Different Physical Appearance. Negative on second collection</u>	<u>19</u>
<u>Case #15 Laboratory C Reported Result: Failed to Reconfirm Marijuana (THC) – Invalid due to Interference</u>	<u>20</u>
<u>Case #16 Split Specimen Laboratory Reported Result: Failed to Reconfirm Cocaine Metabolite (BZE) – BZE not detected</u>	<u>21</u>
<u>Case #17 Laboratory Reported Result: Positive for Marijuana (<math>\Delta</math>9-THC) – 3 ng/mL</u>	<u>22</u>
<u>Case #18 Laboratory Reported Result: Positive for Marijuana (<math>\Delta</math>9-THC) – 14 ng/mL</u>	<u>23</u>
<u>Case #19 Laboratory Reported Result: Positive for 6-Acetylmorphine (6-AM) – 5 ng/mL</u>	<u>24</u>
<u>Case #20 Laboratory Reported Result: Rejected for Testing – Uncorrected Flaw: Collector signature not recovered</u>	<u>25</u>

Case #21 Laboratory Reported Result: Positive for Cocaine – 12 ng/mL and Cocaine Metabolite (BZE) – 25 ng/mL.....26

Case #22 Laboratory Reported Result: Positive for Codeine – 23 ng/mL and Oxycodone – 30 ng/mL .....27

Case #23 Laboratory Reported Result: Positive for Codeine – 35 ng/mL .....28

Case #24 Laboratory Reported Result: Positive for Hydromorphone – 23 ng/mL and Codeine – 31 ng/mL .....30

Case #25 Laboratory Reported Result: Positive for Oxycodone – 37 ng/mL .....31

Case #26 Laboratory Reported Result: Positive for Codeine – 17 ng/mL and Morphine – 59 ng/mL.....32

## **Case #1 Laboratory Reported Result: Positive for Marijuana ( $\Delta^9$ -THC) – 11 ng/mL**

### **Positive Drug (Marijuana)**

**Laboratory Report:** The laboratory sent an electronic report and faxed a copy of the completed Federal Drug Testing Custody and Control Form (CCF) (Copy 1). The information on the electronic report matched the information on the Federal CCF. The collector used the term “express carrier” in Step 4 of the Federal CCF rather than stating the specific name of the delivery service. Otherwise, the Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** A collector is required to provide the specific name of the delivery service on the Federal CCF; however, it is considered an insignificant discrepancy when the correct name is not provided. No action is needed to correct the discrepancy.

Before a final determination can be made, the Medical Review Officer (MRO) must discuss the positive test result with the donor. During the donor interview, the donor claims he tested positive because of passive inhalation. He states that he was at a party on Saturday night at which several individuals were smoking marijuana, but he did not smoke marijuana himself. The Federal CCF documents that the donor’s specimen was collected three days after the claimed passive exposure occurred.

**Conclusion:** Clinical studies have shown that it is highly unlikely that a non-smoking individual could inhale sufficient smoke by passive inhalation to result in a sufficient drug concentration in oral fluid for detection at the cutoff concentrations used in the federal agency program. The circumstances described by the donor do not explain the presence of the marijuana (THC) in the donor’s oral fluid. The MRO may not accept a claim that a laboratory positive THC result is due to passive inhalation of smoked marijuana or ingestion of edible products containing tetrahydrocannabinol (THC).

**MRO Reported Result:** Positive for Marijuana.

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.1.3.3.q, 5.2, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.d.2

Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., and Vandrey, R., Non-Smoker Exposure to Secondhand Cannabis Smoke. III. Oral Fluid and Blood Drug Concentrations and Corresponding Subjective Effects. Journal of Analytical Toxicology, Vol 39, July 2015.

## **Case #2 Laboratory Reported Result: Positive for Morphine – 135 ng/mL**

### **Verified Negative Drug (Morphine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor does not recall using any prescription medications that may have contained codeine or morphine. The donor also does not recall having eaten any poppy seeds around the time of the oral fluid collection. In other words, the donor does not have an explanation for the positive result.

The MRO does not find any clinical evidence of abuse of opiates.

**Conclusion:** When there is no clinical evidence of abuse, and the oral fluid concentration of morphine is less than 150 ng/mL, the MRO is required to report the test result as Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that, within the Department of Health and Human Services (HHS) program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and the Substance Abuse and Mental Health Services Administration (SAMHSA) take no position regarding whether an MRO's independent decision to disclose safety-related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

**MRO Reported Result:** Negative.

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.4.1, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3.i

### **Case #3 Laboratory Reported Result: Positive for Codeine – 143 ng/mL**

#### **Verified Negative Drug (Codeine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and faxed a copy of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor denies using any medication that may have contained codeine or morphine.

The MRO does not find any clinical evidence of abuse of opiates.

**Conclusion:** Although the quantitative test results indicate that a medication containing codeine was most likely taken by the donor, the MRO is required to report a Negative result when there is no clinical evidence of abuse, and the concentrations of codeine or morphine are less than 150 ng/mL.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that, within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

**MRO Reported Result:** Negative.

#### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.4.1, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.3.c.i

## **Case #4 Laboratory Reported Result: Positive for Codeine – 340 ng/mL**

### **Verified Negative Drug (Codeine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and faxed a copy of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor states that he was taking a prescription medication containing codeine (i.e., Tylenol with codeine) at the time of the drug test and the interview. The donor submits a copy of his medical record to prove that the medication was properly prescribed to treat back pain.

**Conclusion:** The donor provided a valid prescription to substantiate the positive codeine result. Therefore, the MRO is not required to determine if there is any clinical evidence of abuse.

**MRO Reported Result:** Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.3, 5.4.1, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2

## **Case #5 Laboratory Reported Result: Positive for Methamphetamine – 192 ng/mL**

### **Positive Drug (Methamphetamine)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor denies taking any prescription medications but states that he had used some over-the-counter (OTC) decongestants and a Vicks® VapoInhaler® at the time of the drug test.

The MRO sends a written request to the laboratory to obtain the quantitative amphetamine result. The laboratory reports an amphetamine concentration of 12 ng/mL.

*Note: Because methamphetamine metabolizes to amphetamine, the presence of amphetamine is consistent with methamphetamine use.*

The MRO requests that the laboratory perform a chiral analysis to determine which enantiomers of methamphetamine are in the specimen. Because *l*-methamphetamine is a legitimate component of some OTC nasal decongestant products, the MRO wants to be certain that the reported methamphetamine is not attributable to using a decongestant inhaler. The laboratory reports that approximately 90 percent of the methamphetamine is the *d*-enantiomer. Some decongestant inhalers contain *l*-methamphetamine (listed in the ingredients as levmetamfetamine); however, *d*-methamphetamine cannot be ascribed to the use of an OTC product.

**Conclusion:** The donor does not have a valid prescription or other authorization to use methamphetamine and does not provide a legitimate medical explanation for the positive drug test result.

### **MRO Reported Result: Positive for Methamphetamine**

*Note: Early in 2016, levmetamfetamine (l-methamphetamine) was removed from the Vicks® VapoInhaler®, and a reformulated inhaler was reintroduced to the market. However, a number of decongestant inhalers on the OTC market contain l-methamphetamine. This ingredient (l-methamphetamine) may also be identified as levmetamfetamine, l-desoxyephedrine, or levomethamphetamine. Examples of current levmetamfetamine products include but are not limited to Amoray® Vaporizing Inhaler (in which it is not listed as an active ingredient), NeilMed Sinu Inhaler®, and Equate® Vapor Inhaler. In addition, Vicks® VapoInhalers® containing l-methamphetamine may remain in some medicine cabinets.*

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.1.1, Appendix F-Table 4, 6

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3



**Case #6 Laboratory Reported Result: Positive for Cocaine – 10 ng/mL and Cocaine Metabolite (Benzoylecgonine [BZE]) – 78 ng/mL**

**Positive Drug (Cocaine, Cocaine Metabolite)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor denies using cocaine but claims that cocaine was used as a topical anesthetic prior to a laryngoscopic procedure. The donor submits a copy of the medical record that documented the use of cocaine for the procedure, and the MRO verifies that use with the physician who performed the procedure. The medical record supports the use of cocaine hydrochloride; however, this drug was used 10 days before the oral fluid specimen was collected.

**Conclusion:** Because the documented use of cocaine occurred 10 days before the drug test, the positive result cannot be attributed to this medical use of cocaine. Generally, the detection window for the cocaine metabolite in oral fluid is two to three days after use when using the cutoff concentrations required for testing federally regulated specimens.

**MRO Reported Result:** Positive for Cocaine and Cocaine Metabolite.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3

## **Case #7 Laboratory Reported Result: Positive for Morphine – 35 ng/mL**

### **Verified Negative Drug (Morphine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and faxed a copy of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor states that he was taking Ultram® (tramadol) at the time that he submitted his oral fluid specimen. The donor also states that he routinely eats poppy seed bagels.

During the interview, the MRO is satisfied that there is no clinical evidence of opiate abuse.

**Conclusion:** The morphine concentration is consistent with eating poppy seeds. Additionally, Ultram® cannot cause an oral fluid specimen to test positive for morphine because tramadol does not metabolize to morphine. When there is no clinical evidence of abuse, and the oral fluid concentration of morphine is less than 150 ng/mL, the MRO is required to report the test result as Negative.

**MRO Reported Result:** Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.3, 5.4.1, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3.i

**Case #8 Laboratory Reported Result: Positive for Methamphetamine – 250 ng/mL and Amphetamine - 30 ng/mL**

**Verified Negative Drugs (Methamphetamine, Amphetamine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and faxed a copy of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory. The MRO had a blanket request on file at the laboratory to receive quantitative amphetamine results for all specimens reported positive for methamphetamine.

**Discussion:** *Note: Because the methamphetamine concentration is significantly higher than the amphetamine concentration, the amphetamine appears to be present as a metabolite of methamphetamine.*

During the interview with the donor, the MRO asks the donor to list the drugs he was taking at the time of the drug test, and the donor states that he was using a decongestant inhaler for sinus congestion and Valium® (diazepam) for anxiety.

*Note: The donor volunteered this information because he thought the Valium® may have caused the positive drug test.*

To determine whether the methamphetamine came from decongestant inhaler use, the MRO requests that the laboratory perform a chiral analysis to determine which enantiomers of methamphetamine are in the specimen. The chiral analysis results show that over 95 percent of the methamphetamine present in the oral fluid was the *l*-enantiomer.

**Conclusion:** The chiral analysis supports the use of an OTC decongestant inhaler as the reason for the positive drug test result.

**MRO Reported Result:** Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual,*

Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.

*Note: Early in 2016, levmetamfetamine (l-methamphetamine) was removed from the Vicks® VapoInhaler®, and a reformulated inhaler was reintroduced to the market. However, a number of decongestant inhalers on the OTC market contain l-methamphetamine. This ingredient (l-methamphetamine) may also be identified as levmetamfetamine, l-desoxyephedrine, or levomethamphetamine. Examples of current levmetamfetamine products include but are not limited to Amoray® Vaporizing Inhaler (in which it is not listed as an active ingredient), NeilMed Sinu Inhaler®, and Equate® Vapor Inhaler. In addition, Vicks® VapoInhalers® containing l-methamphetamine may remain in some medicine cabinets.*

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.3, 5.1.1, 6.3, Appendix F-Table 4, 6

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2

## Case #9 Laboratory Reported Result: Positive for Methamphetamine – 213 ng/mL

### Positive Drug (Methamphetamine)

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory. The MRO had a blanket request on file at the laboratory to receive quantitative amphetamine results for all specimens reported positive for methamphetamine.

**Discussion:** During the interview with the donor, the donor states that he had taken Adipex-P® (phentermine) for weight control, had taken a free sample given to him by his physician (but could not remember the name of the sample), frequently uses an OTC decongestant inhaler for a stuffy nose, and uses several nutritional supplements from a health food store.

The MRO contacts the donor's physician, who indicates that she had given the donor free samples of Tenuate® (diethylpropion HCl) to take before taking Adipex-P®.

The MRO contacts the laboratory and is told that neither diethylpropion nor phentermine metabolize to methamphetamine or amphetamine; however, the OTC decongestant inhaler does contain levmetamfetamine (*l*-methamphetamine). (*Table 6 of the MRO manual lists other drugs that may be metabolized to amphetamine or methamphetamine.*)

To determine whether the decongestant inhaler caused the positive result, the MRO requests that the laboratory conduct a chiral analysis to determine which enantiomers of methamphetamine are in the specimen. The laboratory reports the following results: 37 percent *d*-methamphetamine and 63 percent *l*-methamphetamine.

**Conclusion:** Tenuate® and Adipex-P® are not responsible for the presence of methamphetamine in this oral fluid specimen. None of these products contains methamphetamine or amphetamine, and neither of these products is metabolized to methamphetamine or amphetamine. In addition, nutritional supplements do not explain the drug test results. If the OTC decongestant inhaler were the only source of methamphetamine in this oral fluid, the percentage of *l*-methamphetamine would have been greater than 80 percent. Thus, the donor ingested another source of methamphetamine containing the *d*-isomer.

**MRO Reported Result:** Positive for Methamphetamine.

*Note: An MRO may request enantiomeric testing with a blanket request (i.e., a request for enantiomeric testing of all methamphetamine-positive specimens or all specimens with a positive amphetamine initial test) or on an individual specimen basis. MRO requests are not needed if the laboratory reflexes ALL regulated specimens to enantiomeric testing based on positive initial or confirmatory test results.*

*Note: Early in 2016, levmetamfetamine (*l*-methamphetamine) was removed from the Vicks® VapoInhaler®, and a reformulated inhaler was reintroduced to the market. However, a number of decongestant inhalers on the OTC market contain *l*-methamphetamine. This ingredient (*l*-methamphetamine) may also be identified as levmetamfetamine, *l*-desoxyephedrine, or*

*levomethamphetamine. Examples of current levmetamfetamine products include but are not limited to Amoray® Vaporizing Inhaler (in which it is not listed as an active ingredient), NeilMed Sinu Inhaler®, and Equate® Vapor Inhaler. In addition, Vicks® VapoInhalers® containing l-methamphetamine may remain in some medicine cabinets.*

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.1.1, Appendix F-Table 4, 6

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3

## **Case #10 Laboratory Reported Result: Invalid Result – Immunoassay Interference**

### **Cancelled Test (Invalid Specimen); Immunoassay Interference and SVT (Albumin, IgG)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** The MRO discusses the results with the donor, and the donor denies tampering with the oral fluid specimen. To obtain additional information, the MRO requests additional Specimen Validity Testing (SVT) testing for Tube A using albumin and immunoglobulin G (IgG). Albumin and IgG are biomarkers that can be used to determine if the oral fluid specimen is valid. The oral fluid SVT results indicate an invalid specimen with albumin and IgG below the laboratory's limit of detection/limit of quantification (LOD/LOQ).

*Note: Oral fluid drug testing does not routinely include specimen validity testing (SVT). The MRO may order SVT when the 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,*

**Conclusion:** The MRO is required to contact the donor and give the donor an opportunity to explain the Invalid result. For this oral fluid specimen, the SVT and Invalid results provide additional information that may be useful if the donor requests that the split (Tube B) specimen be tested by a second certified laboratory. If a laboratory is unable to perform or complete testing of a primary specimen, the MRO may request that the specimen be sent to another HHS-certified laboratory for additional/different testing.

**MRO Reported Result:** Cancelled Test: Invalid Specimen: Immunoassay interference and Abnormal SVT. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure and reports the cancelled test to the appropriate regulatory office.

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.2, 4.3, 4.5.1, 5.6.4.1.b, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.e.2

**Case #11 Laboratory Reported Result: Adulterated (Specify Adulterant) Present = (confirmatory test value) and Invalid Result – Tube A and Tube B – Different Physical Appearance**

**Refusal to Test (Adulterated)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** The laboratory contacts the MRO to discuss the invalid result *prior* to reporting. The MRO discusses the results with the donor, and the donor denies tampering with the oral fluid specimen.

**Conclusion:** Although the MRO is required to contact the donor and give the donor an opportunity to explain the adulterated result, the criteria established by the Mandatory Guidelines to report a specimen as adulterated preclude any legitimate medical explanation for the presence of an adulterant. For this oral fluid specimen, the invalid result provides additional information that may be useful if the donor requests that the split (Tube B) specimen be tested by a second certified laboratory. The fact that Tube A and Tube B have a different physical appearance may suggest that the identified adulterant would not be reconfirmed in the split (Tube B) specimen.

Generally, the MRO reports all positive, adulterated, invalid, and (for urine) substituted results to the Federal agency. However, in this case, the MRO should report only the adulterated result to the agency. The MRO only reports the invalid result to the agency if the split specimen is tested and fails to reconfirm as adulterated. The reason for the invalid result (Tube A and Tube B – Different Physical Appearance) will most likely have an impact on the reported result if the donor requests that the split (Tube B) specimen be tested for the adulterant reported in the primary (Tube A) specimen.

**MRO Reported Result:** Refusal to Test (Adulterated).

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.2, 4.3, 5.6.3.2, 5.6.4.1.b, , Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.b.2 and 13.5.d.2



**Case #12 Laboratory Reported Result: Positive for Marijuana ( $\Delta$ 9-THC) – 2 ng/mL, Cocaine - 21 ng/mL, and Cocaine Metabolite (BZE) – 35 ng/mL**

**Positive Drugs (Cocaine, Cocaine Metabolite, Marijuana)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor claims that he tested positive for marijuana because he was at a party and had eaten brownies that contained marijuana and that he tested positive for cocaine because a dentist had used lidocaine prior to a dental procedure. The Federal CCF documented that the donor's specimen was collected two days after he claimed to have eaten the brownies and one day after the dental procedure.

**Conclusion:** Donors have claimed unknowingly ingesting marijuana in brownies to explain positive test results for many years. Given the current concentrations of THC found in edibles, it is possible that after ingesting brownies, a donor's oral fluid drug test may be positive for the marijuana THC. The MRO may not accept a claim that a laboratory positive result is the result of passive inhalation or ingestion of edible products containing THC. With regard to the cocaine metabolite, lidocaine does not contain cocaine and does not metabolize to either cocaine or the cocaine metabolite.

**MRO Reported Result:** Positive for Marijuana, Cocaine and Cocaine Metabolite.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.2, 5.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3

**Case #13 Laboratory Reported Result: Rejected for Testing – Fatal Flaw: Tube A label/seal broken**

**Cancelled Test (Fatal Flaw: Label/Seal Broken)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** The Mandatory Guidelines designate some specific specimen and documentation problems as either “fatal flaws” or “correctable flaws.” Laboratories generally identify fatal flaws during receipt and accessioning and do not test such specimens or stop testing if the flaw is identified after testing has been initiated. For errors that require the laboratory to reject the specimen if not corrected, the laboratory must accession and hold the specimen while taking action to resolve the problem (i.e., by obtaining a memorandum for the record [MFR], from the collector). The laboratory must delay testing the specimen until the collector provides the documentation to recover these correctable flaws.

A broken seal on a primary (Tube A) specimen is a fatal flaw unless the split (Tube B) specimen can be redesignated as the primary (Tube A) specimen. Tube B may be redesignated as Tube A if the volume of oral fluid in Tube B is sufficient to conduct the required tests, and the tube seal is intact. In that case, the laboratory will test Tube B and report a result. When redesignation occurs, the laboratory notes the redesignation on the CCF. If and when the specimen is reported Positive, Invalid, or Adulterated, and the donor requests a retest of the split (Tube B) specimen, the laboratory will inform the MRO that a split specimen is not available.

**Conclusion:** Because the laboratory rejected the specimen for testing, and there was no documentation of redesignation, the MRO confirmed with the laboratory that it was not possible to redesignate the specimens (i.e., Tube B as Tube A).

**MRO Reported Result:** Test Cancelled: Fatal Flaw: Tube A seal broken. The MRO reports the cancellation and the reason to the federal agency, which then determines whether or not to immediately collect another oral fluid specimen from the donor.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.1.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.1.b

**Case #14 First Laboratory Reported Result: Negative and Invalid – Tube A and Tube B – Different Physical Appearance. Negative on second collection**

**Cancelled Test (Different Physical Appearance); Negative Test (Recollection)**

**Laboratory Report:** The laboratory sent an electronic report and faxed the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

*Note: Laboratories are required to test Tube A when a specimen meets the criteria for reporting as Invalid based on Tube A and Tube B – Different Physical Appearance. Prior to reporting the Invalid result (Tube A and Tube B-Different Physical Appearance), the laboratory must contact the MRO to decide whether additional/different testing would be of use to obtain a definitive result.*

**Discussion:** The CCF includes no collector or laboratory remarks indicating a problem with the collection or the specimen. During the interview with the donor, the donor gives no explanation for the Invalid result. He denies having tampered with the specimen.

**Conclusion:** The contents of Tube A and Tube B appear not to represent a proper split specimen collection or that something was added to one tube but not the other.

**MRO Reported Result:** Test Cancelled: Invalid Result–Different Physical Appearance. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure and reports the cancelled test to the appropriate regulatory office.

**Second (Recollection) Laboratory Report: Negative.**

The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1) to the MRO. The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** This is the second specimen collected.

**Conclusion:** The specimen result is valid. The MRO reports the result.

**MRO Reported Result:** Negative.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.2, 5.6.4, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 3.8.d

**Case #15 Laboratory C Reported Result: Failed to Reconfirm Marijuana (THC) – Invalid due to Interference**

**Test Cancelled (Failed to Reconfirm)**

**Split Specimen Laboratory Report:** Failed to Reconfirm for Marijuana (THC) –Reason: Invalid Result–LC-MS/MS interference.

**Discussion:** Laboratory B received the split (Tube B) specimen from the primary laboratory with a copy of the MRO’s request to test the split specimen for marijuana (THC), the drug that was reported positive in the primary (Tube A) specimen. When Laboratory B was unable to reconfirm the presence of THC, the laboratory consulted with the National Laboratory Certification Program (NLCP) to identify another HHS-certified laboratory that may be able to perform the test needed to reconfirm or refute the primary (A) specimen results. Laboratory B contacted the MRO to provide information to assist the MRO in deciding whether to send the split specimen to a third laboratory (Laboratory C). After discussing the results with Laboratory B, the MRO decides to send the specimen to Laboratory C for split specimen (B) testing.

**Laboratory B Report:** Laboratory B does not issue a report for a split specimen that fails to reconfirm when the MRO decides to send the split specimen to Laboratory C

**Laboratory C Report:** Laboratory C faxed a copy of the completed Federal CCF (Copy 1) and its Split Specimen Report for the specimen. Laboratory C properly completed Step 5b on the Federal CCF. The Split Specimen Report contained additional explanatory information as required, including the results of invalid due to confirmatory test method (LC-MS/MS) interference, and was signed and dated by the certifying scientist.

**Discussion:** Laboratory C received the split (Tube B) specimen from the Laboratory B with a copy of the MRO’s request to retest the split specimen for marijuana (THC), the drug that was reported positive in the primary (Tube A) specimen. Laboratory C was also unable to reconfirm the presence of THC due to interference.

**Conclusion:** Laboratory C Failed to Reconfirm marijuana (THC) due to interference with the LC-MS/MS THC method.

**MRO Reported Result:** Failed to Reconfirm for Marijuana (THC), Invalid Result–LC-MS/MS interference, and Test Cancelled for both the primary and split specimens. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure and reports the failed to reconfirm and cancelled test to the appropriate regulatory office.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 3.2.4.2, 5.6.4, Appendix F-Table 4, 5

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 14.6.e

**Case #16 Split Specimen Laboratory Reported Result: Failed to Reconfirm Cocaine Metabolite (BZE) – BZE not detected**

**Test Cancelled (Failed to Reconfirm)**

**Split Specimen Laboratory Report:** Laboratory B faxed a copy of the completed Federal CCF (Copy 1) and its Split Specimen Report for the specimen. Laboratory B properly completed Step 5b on the Federal CCF. The Split Specimen Report contained additional explanatory information as required, and was signed and dated by the certifying scientist.

**Discussion:** Laboratory B received the split (Tube B) specimen from the primary laboratory with a copy of the MRO's request to test the split specimen for BZE, the drug metabolite reported positive in the primary (Tube A) specimen. The copy of the Federal CCF (Copy 1) sent with the specimen documented Laboratory A's reported concentration of 20 ng/mL BZE. When Laboratory B was unable to reconfirm the presence of BZE and there was no evidence to support reporting an Invalid result, results were reported as Failed to Reconfirm.

If Laboratory B believes that BZE may be present in the split specimen but cannot obtain a valid result (e.g., because of an interferent affecting its assay), Laboratory B must contact the MRO to decide whether testing at a third laboratory would be useful. In this case, Laboratory B did not contact the MRO to discuss this possibility because its confirmatory drug test indicated that BZE was not present in the split (Tube B) specimen.

**Conclusion:** There is no apparent reason for the discrepancy in the results for the primary (Tube A) and split (Tube B) specimens.

**MRO Reported Result:** Failed to Reconfirm for Cocaine Metabolite and Test Cancelled for both the primary and split specimens. The MRO reports the failed to reconfirm and cancelled test to the appropriate regulatory office.

*Note: The Mandatory Guidelines do not require the MRO to direct the agency to complete an additional collection. This case does not state that a Negative result is needed for a federal agency applicant/pre-employment, return-to-duty, or follow-up test; however, if the agency needs a Negative result for any of those purposes, the agency can request a second collection.*

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 3.2.4.2, Appendix F-Table 4, 5

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 14.6.h

## **Case #17 Laboratory Reported Result: Positive for Marijuana ( $\Delta$ 9-THC) – 3 ng/mL**

### **Positive Drug (Marijuana); CBD use**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor admits cannabidiol (CBD) use. The donor produces a bottle of CBD, which is legal in the donor's state of residence. The donor claims that he consumes multiple doses daily of CBD products to alleviate back pain and to treat his diabetes.

**Conclusion:** A positive test can result from cannabis use or use of a CBD product that contains THC. Under the Federal Drug-Free Workplace Program, there is no legitimate medical explanation for a marijuana positive test result other than a verified prescription for Marinol®, Sativex® or generic equivalent. The donor's CBD use may be consistent with the positive drug test result and does not constitute a legitimate medical explanation for the drug test result.

**MRO Reported Result:** Positive for Marijuana.

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.2, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2.ii

## **Case #18 Laboratory Reported Result: Positive for Marijuana ( $\Delta 9$ -THC) – 14 ng/mL**

### **Positive Drug (Marijuana); Medical Marijuana**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor admits marijuana use. However, the donor produces an order for medical marijuana, which is legal in the donor's state of residence. The donor claims that his physician prescribed marijuana to alleviate shoulder pain from a previous work injury and states that he only uses marijuana on weekends when he does not work.

**Conclusion:** The donor's marijuana use is consistent with the positive drug test result. At this time, marijuana remains a Schedule I drug, and medical marijuana use is not an acceptable medical explanation for a positive drug test result in any federal agency drug testing program. A written recommendation from a licensed physician or medical professional does not exempt the donor from this rule. If the donor admits the use of medical marijuana, the MRO verifies the result as positive.

**MRO Reported Result:** Positive for Marijuana.

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.2, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2.iii

**Case #19 Laboratory Reported Result: Positive for 6-Acetylmorphine (6-AM) – 5 ng/mL**

**Positive Drug (6-AM)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** Note: Although morphine is generally present (i.e., at or above the program cutoff of 15 ng/mL) in positive 6-AM specimens, morphine may not be present or may be present below 15 ng/mL in a positive 6-AM specimen for several reasons. For example, the donor may have used heroin close to the time of collection; the donor may have a metabolic defect in the metabolism of 6-AM, resulting in prolonged excretion; the donor's morphine metabolic pathways may have been altered; or another substance may have interacted with 6-AM or morphine.

During the interview with the donor, the donor denies heroin use.

**Conclusion:** When a laboratory reports a specimen as positive for the heroin metabolite (6-AM), it is proof of heroin use. There is no legitimate medical explanation for a positive 6-AM result.

**MRO Reported Result:** Positive for 6-AM.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 5.4.4, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2.iii



## **Case #20 Laboratory Reported Result: Rejected for Testing – Uncorrected Flaw: Collector signature not recovered**

### **Cancelled Test; Collector Errors; MRO Responsibilities**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1) and an MFR from the collector. The collector had printed his name but had not signed the Federal CCF in Step 4. A missing collector signature is a recoverable flaw. The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the laboratory.

**Discussion:** The Mandatory Guidelines designate some specific specimen and documentation problems as either “fatal flaws” or “correctable flaws.” Laboratories generally identify fatal flaws during receipt and accessioning and do not test such specimens or stop testing if the flaw is identified after testing has been initiated. For errors that require the laboratory to reject the specimen if not corrected, the laboratory must accession and hold the specimen while taking action to resolve the problem (i.e., by obtaining a memorandum for the record [MFR], from the collector). The laboratory must delay testing the specimen until the collector provides the documentation to recover these correctable flaws.

The laboratory faxed a MFR to the collector to recover the missing signature. After 5 business days, the collector had not responded to the MFR and the laboratory reported Rejected for Testing: Uncorrected Flaw: Collector signature not recovered result to the MRO.

In reviewing his records, the MRO notes that the same collector had omitted his signature on the CCF for another specimen collected one week earlier. The MRO should monitor the frequency of documentation errors, notify the responsible party (e.g., collector, laboratory) when an error occurs more than once a month, and direct them to take corrective action to prevent recurrence of the errors.

**Conclusion:** The laboratory reported Rejected for Testing after waiting 5 business days to recover the missing collector signature.

**MRO Reported Result:** Test Cancelled and Remark: Rejected for Testing-Uncorrected Flaw: Collector signature not recovered. The MRO reports the cancellation and the reason to the federal agency, which then determines whether or not to immediately collect another oral fluid specimen from the donor.

**Additional MRO Actions:** The MRO should send a letter notifying the collector employer or collector (if self-employed) of the errors and the need for corrective action. The MRO should also send a copy of the letter to the federal agency for follow-up.

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.1.3.2.a, 4.1.5, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 15.2.a

**Case #21 Laboratory Reported Result: Positive for Cocaine – 12 ng/mL and Cocaine Metabolite (BZE) – 25 ng/mL**

**Positive Drugs (Cocaine, Cocaine Metabolite); Collector Errors; MRO Responsibilities**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1) and an MFR from the collector. The collector had printed his name but had not signed the Federal CCF in Step 4. A missing collector signature is a recoverable flaw. The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the laboratory.

**Discussion:** The Mandatory Guidelines designate some specific specimen and documentation problems as either “fatal flaws” or “correctable flaws.” Laboratories generally identify fatal flaws during receipt and accessioning and do not test such specimens or stop testing if the flaw is identified after testing has been initiated. For errors that require the laboratory to reject the specimen if not corrected, the laboratory must accession and hold the specimen while taking action to resolve the problem (i.e., by obtaining a memorandum for the record [MFR], from the collector). The laboratory must delay testing the specimen until the collector provides the documentation to recover these correctable flaws.

The laboratory faxed a MFR to the collector to recover the missing collector signature. The collector responded to the MFR within 5 business days. The collector’s MFR response addresses the signature omission and was sent to the laboratory the day after specimen receipt. There are no other problems with the submitted documents. The MRO conducts the donor interview and reports the specimen as Positive for Cocaine and Cocaine Metabolite to the federal agency.

In reviewing his records, the MRO notes that the same collector had omitted his signature on the CCF for another specimen collected one week earlier. The MRO should monitor the frequency of documentation errors, notify the responsible party (e.g., collector, laboratory) when an error occurs more than once a month, and direct them to take corrective action to prevent recurrence of the errors.

**MRO Reported Result:** Positive for Cocaine and Cocaine Metabolite

**Additional MRO Actions:** The MRO should send a letter notifying the collector employer or collector (if self-employed) of the errors and the need for corrective action. The MRO should also send a copy of the letter to the federal agency for follow-up.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.1.3.2.a, 5.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.3 and 15.2.a

**Case #22 Laboratory Reported Result: Positive for Codeine – 23 ng/mL and Oxycodone – 30 ng/mL**

**Positive Drug (Oxycodone); Verified Negative Drug (Codeine)**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor states that he was taking a prescription medication—APAP #4—at the time of the drug test and the interview. The donor submits a copy of his medical record to prove that the medication was properly prescribed to treat back pain. The donor is unable to provide additional medical information.

**Conclusion:** Although the donor provides documentation to support the laboratory findings of codeine, the documentation provided does not support the finding of oxycodone.

**MRO Reported Result:** Positive for Oxycodone.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.2, 4.5.3, 5.4.1, 5.4.2, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2 and 13.5.c.3

## Case #23 Laboratory Reported Result: Positive for Codeine – 35 ng/mL

### Verified Negative Drug (Codeine); Possible Safety Concerns

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor states that, at the time of the drug test and the interview, he was using a fentanyl patch prescribed for pain control after recent back surgery. He also reports contracting a recent upper respiratory infection (URI) from his spouse. During his last URI, he remembered using a behind-the-pharmacy-counter cough preparation containing codeine, which he obtained from the local pharmacy. The donor submits a copy of the pharmacy record showing that he had received a codeine cough preparation the same day as the specimen collection.

**Conclusion:** Fentanyl will not cause a positive test result under the Federal Drug-Free Workplace Program. Codeine preparations are available behind the pharmacy counter in some states, but their distribution must be recorded by the pharmacist. The MRO must ensure that the codeine cough preparation was dispensed prior to the time the specimen was collected. The codeine level measured in this case was less than 150 ng/mL and was likely attributable to the legitimate use of a codeine medication.

**MRO Reported Result:** Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to drug information disclosed by the donor during the interview with the MRO (i.e., use of a prescription drug that is not tested under the federal program) or a drug reported as Positive by the laboratory that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

### References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.2, 5.4.1, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2

**Case #24 Laboratory Reported Result: Positive for Hydromorphone – 23 ng/mL and Codeine – 31 ng/mL**

**Verified Negative Drugs (Hydromorphone, Codeine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the MRO, the donor states that at the time of the drug test and the interview, he was taking Dilaudid® (hydromorphone), which was prescribed for pain control after a recent femur fracture. He provides a report from his personal physician and records from the pharmacy showing the drug was dispensed one week before the specimen collection. He offers no records or comment regarding the codeine found.

Additionally, the MRO does not find any clinical evidence of abuse of opiates.

**Conclusion:** The Dilaudid prescription would justify the laboratory findings, but hydromorphone does not metabolize to codeine. When there is no clinical evidence of abuse, and the oral fluid concentration of codeine is less than 150 ng/mL, the MRO is required to report the test result as Negative.

**MRO Reported Result:** Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.3, 5.4.1, 5.4.2, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2 and 13.5.c.3

## **Case #25 Laboratory Reported Result: Positive for Oxycodone – 37 ng/mL**

### **Verified Negative Drug (Oxycodone); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor states that she had been taking OxyContin® (oxycodone) since she slipped and fell on her tail bone 14 months ago. The donor submits a copy of her medical record to prove that the medication was properly prescribed and a record from the pharmacy showing that the medication was dispensed prior to the specimen collection date.

**Conclusion:** The MRO made a determination regarding the validity of the prescription. In this case, the donor provided documentation consistent with the laboratory report of oxycodone.

**MRO Reported Result:** Negative.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*

### **References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (January 1, 2020; rev. 0124), Sections 4.5.3, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2

**Case #26 Laboratory Reported Result: Positive for Codeine – 17 ng/mL and Morphine – 59 ng/mL**

**Verified Negative Drugs (Codeine, Morphine); Possible Safety Concerns**

**Laboratory Report:** The laboratory sent an electronic report and an image of the completed Federal CCF (Copy 1). The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the collector and the laboratory.

**Discussion:** During the interview with the donor, the donor states that while shoveling snow to go to work, he immediately experienced severe back pain. He says the pain was similar to what he experienced when he had a disc rupture five years ago. Because he had some pain medication left over from a root canal 13 months ago, and the expiration date of the medication had not passed, he took it for his pain. The medication was originally prescribed to be taken on an as-needed basis. He reports that the label said APAP #4 (codeine). He rested for the next three days, and because the pain medication was working, he did not seek medical attention. He subsequently felt better and went to work the day they were conducting drug testing. The donor submits a copy of the prescription bottle showing the dentist's name and date, which was, in fact, 13 months prior to the drug test. The donor is unable to provide additional medical information.

**Conclusion:** The donor has a valid prescription for the lawful possession of codeine that specifies no time limitations on the use of the drug (even if the expiration date on the dispensed prescription has expired). The prescription would justify the laboratory finding for codeine but not for morphine. Morphine, as a metabolite of codeine, would not be expected to be detected in oral fluid in concentrations greater than codeine. When there is no clinical evidence of abuse, and the oral fluid concentration of morphine is less than 150 ng/mL, the MRO is required to report the test result as Negative.

Additionally, the MRO does not find any clinical evidence of abuse of opiates.

*Note: This case introduces the question of what the MRO should do in the case of safety concerns related to the presence of a drug reported as Positive by the laboratory but that is reported as Negative by the MRO.*

*The MRO Guidance Manual states that within the HHS program, the MRO is not required to discuss safety aspects of the donor's job function. An MRO's decision to contact an employer regarding safety issues related to a donor's valid prescription (i.e., legal drug use) is subject to the MRO's independent and voluntary choice and any obligations the MRO may have with the donor's employing agency. Therefore, before discussing aspects of job safety with an agency, the MRO should review the terms of their service agreement with the agency and any agency policies or rules that govern issues related to safety and/or seek private legal counsel. HHS and SAMHSA take no position regarding whether an MRO's independent decision to disclose safety related information (or other drug testing information, such as numerical values) in the context of a donor's legal drug use is legal or appropriate in any given circumstance because this issue is outside the scope of the Mandatory Guidelines. Please refer to the MRO Guidance Manual, Chapter 6, Section 6.3, Occupational and Public Safety, regarding handling safety issues involving valid prescriptions.*



**MRO Reported Result:** Negative.

**References:**

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (February 1, 2024), Sections 4.5.3, 5.4.1, 6.3, Appendix F-Table 4

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 88 FR 70814 (dated October 12, 2023) effective October 10, 2023, Section 13.5.c.2