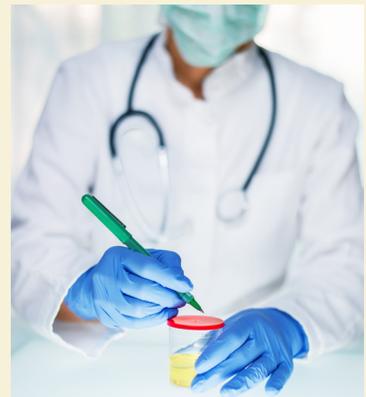


Medical Review Officer Case Studies



Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs

2018 Medical Review Officer (MRO) Case Studies

These case studies provide examples to supplement the Department of Health and Human Services (HHS) MRO Guidance Manual, effective October 1, 2017.

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 Urine (January 23, 2017 Federal Register, 82 FR 7920), effective October 1, 2017.

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>

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Case #1

Specimen Test Result: Positive for Marijuana Metabolite (Δ^9 -Tetrahydrocannabinol-9-Carboxylic Acid [Δ^9 -THCA])—30 ng/mL.

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 two 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 urine 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 metabolite in the donor’s urine. The MRO may not accept a claim that a laboratory positive result is due to passive inhalation or ingestion of edible products containing tetrahydrocannabinol (THC).

MRO Report: Positive for Marijuana Metabolite.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.1.3.3.o, page 4-8; item 7.1.2.b, pages 7-6 to 7-7.

Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.5.d.1.

Case #2

Specimen Test Result: Positive for Morphine—5,200 ng/mL.

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 urine collection. In other words, the donor does not have an explanation for the positive result.

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

Conclusion: When there is no clinical evidence of abuse, and the concentration of morphine is less than 15,000 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 Report: Negative.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.4.1, page 5-6; item 6.3, page 6-6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #3

Specimen Test Result: Positive for Codeine—4,800 ng/mL and Morphine—2,500 ng/mL.

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 and morphine are less than 15,000 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 Report: Negative.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.4.1, page 5-6; item 6.3, page 6-6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #4

Specimen Test Result: Positive for Codeine—17,340 ng/mL and Morphine—6,350 ng/mL.

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 and morphine results. Therefore, the MRO is not required to determine if there is any clinical evidence of abuse.

MRO Report: 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 (October 1, 2017, Rev. 0318), item 4.5.3, pages 4-19 to 4-21; item 5.4.1, page 5-6; item 6.3, page 6-6; Table 4.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #5

Specimen Test Result: Positive for Methamphetamine—950 ng/mL.

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 145 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 Report: Positive for Methamphetamine

Note: *Early in 2016, 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 may also be identified as levmetamfetamine, L-desoxyephedrine, or levmethamphetamine. 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 (October 1, 2017, Rev. 0318), item 5.1.1, pages 5-2 to 5-3; item 7.1.1, pages 7-2 to 7-4; Table 6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 3.5.

Case #6

Specimen Test Result: Positive for Cocaine Metabolite (Benzoylecgonine [BZE])–1,200 ng/mL.

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 urine 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 urine is two to three days after use when using the cutoff concentrations required for testing federally regulated specimens.

MRO Report: Positive for Cocaine Metabolite.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.3, page 5-5.

Case #7

Specimen Test Result: Positive for Morphine—3,150 ng/mL.

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 urine specimen. The donor also states that he routinely eats poppy seed bagels.

Conclusion: The morphine concentration is consistent with eating poppy seeds. During the interview, the MRO is satisfied that there is no clinical evidence of opiate abuse. Additionally, Ultram® cannot cause a urine specimen to test positive for morphine because tramadol does not metabolize to morphine.

MRO Report: 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 (October 1, 2017, Rev. 0318), item 4.5.3, pages 4-19 to 4-21; item 5.4.1, page 5-6; item 6.3, page 6-6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #8

Specimen Test Result: Positive for Methamphetamine—1,250 ng/mL with 225 ng/mL Amphetamine.

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 results show that over 95 percent of the methamphetamine and amphetamine present in the urine were the *l*-enantiomers.

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

MRO Report: 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 (October 1, 2017, Rev. 0318), item 4.5.3, pages 4-19 to 4-21; item 5.1.1, pages 5-2 to 5-3; item 6.3, page 6-6; item 7.1.1, pages 7-1 to 7-4; Table 6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #9

Specimen Test Result: Positive for Methamphetamine—942 ng/mL with 250 ng/mL Amphetamine.

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 a 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 decongestant inhaler does contain *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: Neither Tenuate® nor Adipex-P® was responsible for the presence of methamphetamine or amphetamine in this urine specimen. Neither 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 decongestant inhaler were the only source of methamphetamine in this urine, 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 Report: 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.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.1.1, pages 5-2 to 5-3; item 7.1.1, pages 7-1 to 7-4; Table 6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 3.5.

Case #10

Specimen Test Result: Adulterated; Nitrite = 850 mcg/mL.

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 claims to have been eating cured meats for dinner.

Conclusion: Based on the information available, eating foods containing nitrite or nitrates could not cause the nitrite concentration in a urine specimen to be at or above the 500-mcg/mL cutoff concentration for nitrite adulteration. The donor did not have a legitimate explanation for the presence of nitrite.

MRO Report: Refusal to Test [Adulterated–Nitrite].

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 7.2, pages 7-15 to 7-19).

Case #11

Specimen Test Result: Invalid Result; Oxidant Activity ≥ 50 mcg/mL Chromium(VI) equivalents.

Laboratory Report: 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. Before reporting an Invalid result to the MRO based on oxidant activity, the laboratory must attempt to contact the MRO to decide whether additional testing at a different laboratory would facilitate obtaining a definitive result. In this case, the laboratory and MRO discussed the result and agreed that additional testing was not necessary.

Discussion: During the interview with the donor, the donor claims to have no idea how an oxidant could be in her urine specimen. When encountering this situation, the MRO may evaluate all comments, medications, and medical conditions that might be verified and account for any oxidative activity in the specimen.

Conclusion: The donor did not provide a legitimate medical explanation.

MRO Report: Test Cancelled [Invalid Result–Oxidant Activity]. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

Note: The references allow the reporting of an Invalid result if the oxidant is verified using a general oxidant colorimetric test (with a value equal to or greater than the 50-mcg/mL chromium(VI) equivalent cutoff). Most laboratories use the nitrite equivalent results when the nitrite concentration is equal to or greater than 200 mcg/mL; however, the reporting of chromium(VI) equivalents is allowed.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 7.4, pages 7-20 to 7-21; item 5.6.4, pages 5-10 to 5-12.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 11.19.h.3.

Case #12

Specimen Test Result: Adulterated–Nitrite = 1800 mcg/mL and Invalid Result–Bottle A and Bottle B–Different Physical Appearance.

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 urine 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 urine specimen, the Invalid result provides additional information that may be useful if the donor requests that the split (Bottle B) specimen be tested by a second certified laboratory. The fact that Bottle A and Bottle B have different physical appearances may suggest that the nitrite would not be reconfirmed in the split (Bottle B) specimen.

Generally, the MRO reports all Positive, Adulterated, Substituted, and Invalid results to the federal agency. However, in this case, the MRO reports only the Adulterated result to the agency. Reporting both Refusal to Test (Adulterated) and Test Cancelled (Invalid Result) for the same urine specimen is confusing. The reason for the Invalid result (Bottle A and Bottle B–Different Physical Appearance) will most likely affect only the testing of the split (Bottle B) specimen if the donor requests that the split (Bottle B) specimen be tested for nitrite, as reported in the primary (Bottle A) specimen. The MRO should only report the Invalid result if the split specimen was tested and reported by the laboratory as failed to reconfirm.

MRO Report: Refusal to Test [Adulterated–Nitrite].

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.2.2, pages 4-14 to 4.15; item 4.3.1, page 4-15; item 7.2, pages 7-15 to 7-19; Appendix D, page D-6; Table 4.

Case #13

Specimen Test Result: Positive for Morphine—5,000 ng/mL and Adulterated—Chromium(VI) = 90 mcg/mL.

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 laboratory had the capability to confirm chromium(VI).

Discussion: During the interview with the donor, the donor states that he does not know why his specimen was positive for morphine or why it was reported as Adulterated.

Conclusion: The concentration of morphine in the urine specimen is consistent with the donor having possibly consumed poppy seeds. Therefore, the morphine drug test result is reported as Negative; however, for the Adulterated result, no legitimate medical explanation is provided for the presence of a highly toxic oxidant in the urine specimen.

MRO Report: Refusal to Test [Adulterated—Chromium(VI)].

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.2.2, pages 4-14 to 4-15; item 7.2, pages 7-15 to 7-19).

Case #14

Specimen Test Result: Positive for Marijuana Metabolite (Δ 9-THCA)–60 ng/mL and Cocaine Metabolite (BZE)–120 ng/mL.

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 three 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 urine drug test would be positive for the marijuana metabolite. With regard to the cocaine metabolite, lidocaine does not contain cocaine and does not metabolize to the cocaine metabolite. 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.

MRO Report: Positive for Marijuana Metabolite and Cocaine Metabolite.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 7.1.2, pages 7-4 to 7-7; item 7.1.3, pages 7-7 to 7-9.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.5.d.1.

Case #15

Specimen Test Result: Substituted–Creatinine = 1.5 mg/dL and Specific Gravity = 1.0005.

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 to have been performing strenuous activity and drinking large amounts of fluid for several days prior to the collection procedure because it was hot outside.

The HHS criteria for identifying substituted specimens are based on the physiological ranges of creatinine concentrations and specific gravity values of normal human urine. When a reason is given for a Substituted result, the MRO must decide if the donor is providing a legitimate medical explanation. When a medical explanation is provided, the MRO should request that the agency have the donor provide another urine specimen using a direct observed collection procedure. The MRO should not report the final result to the agency until the laboratory reports the test result for the second specimen. The criteria for Substituted based on those established by HHS essentially eliminate the possibility that the thresholds will be exceeded by normal function of the human body.

In this case, the laboratory reports that the second specimen, collected under direct observation, has a creatinine concentration of 5.5 mg/dL and a specific gravity of 1.003.

Conclusion: The creatinine and specific gravity results for the second specimen are not similar to those for the first specimen. The donor's explanation that he drank large quantities of fluids prior to the first test is not a legitimate explanation for the Substituted result.

MRO Report: Refusal to Test [Substituted].

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.2.2, pages 4-14 to 4-15; item 5.6.2, pages 5-9 to 5-10; Appendix D, page D-3; Table 4.

Case #16

Specimen Test Result: Negative and Dilute—Creatinine = 6.2 mg/dL and Specific Gravity = 1.002.

Laboratory Report: The laboratory reported the specimen using a computer-generated electronic report.

Discussion: The MRO is not required to interview a donor whose urine specimen is reported as Negative for drugs and dilute.

Conclusion: A dilute result may indicate that a donor intentionally consumed large amounts of fluid or took diuretics in an attempt to reduce any drug concentrations to below the cutoffs used; however, this is not necessarily the case. A donor could provide a dilute specimen in other situations (e.g., the donor was allowed too much fluid to drink to provide a specimen when required at the collection site).

MRO Report: Negative and Dilute. The MRO directs the agency to immediately collect another specimen from the donor (i.e., notifying the donor to report to the collection site without delay). The second collection is not to be a direct observed collection.

Second Collection Specimen Test Result: Negative and Dilute—Creatinine = 8.0 mg/dL and Specific Gravity = 1.002

Discussion: If the recollected specimen provides a negative or negative/dilute result, the MRO should report a Negative result to the agency, with no further action required.

Conclusion: A second dilute finding may indicate that a donor can produce urine that meets the program criteria for dilution under some conditions, including working in hot weather conditions and drinking large amounts of fluid, taking a diuretic, drinking caffeinated beverages, drinking fluids immediately before providing the specimen, or drinking fluid to provide a specimen when required at the collection site.

MRO Report: Negative.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.6, page 5-9; item 7.3, pages 7-19 to 7-20; Table 4.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.5.b.1.

Case #17

Specimen Test Result: Substituted–Creatinine = 1.0 mg/dL and Specific Gravity = 1.0005 and Invalid Result–Abnormal pH = 4.0.

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 does not know why his urine specimen was reported as Substituted and Invalid.

The MRO informs the donor that he has the right to request that the split (Bottle B) specimen be tested in a second laboratory for the Substituted result but not for the Invalid result.

Conclusion: The Substituted result is considered a Refusal to Test, but the Invalid result (by itself) would normally lead to a cancelled test and immediate collection of a second specimen using a direct observed collection procedure. The MRO should report only the Substituted result to the agency. If the donor requests a split (Bottle B) retest at a second certified laboratory, and the Substituted result is not reconfirmed, the MRO can then report the Invalid result to the federal agency. Whereas both a failure to reconfirm and an Invalid result will lead to a cancelled test and immediate recollection using direct observation, the MRO will have Invalid result information for the first specimen to review when he/she reviews the recollected specimen's test results.

MRO Report: Refusal to Test [Substituted].

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.3.1.b, page 4-15; item 4.2.2, pages 4-14 to 4-15; item 5.6.2, pages 5-9 to 5-10; Appendix D, page D-4; Table 4.

Case #18

Specimen Test Result: Rejected for Testing–Fatal Flaw: Bottle A 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 (Bottle A) specimen is fatal unless the split (Bottle B) specimen can be redesignated as the primary (Bottle A) specimen. Bottle B may be redesignated as Bottle A if the volume of urine in Bottle B is sufficient to conduct the required tests, and the bottle seal is intact. In that case, the laboratory will test Bottle B and report a result. When redesignation occurs, the laboratory notes the redesignation on the CCF. If and when the specimen is reported Positive, Adulterated, or Substituted, and the donor requests a retest of the split (Bottle 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 knew that it was not possible to redesignate the specimens (i.e., Bottle B as Bottle A).

MRO Report: Test Cancelled: Fatal Flaw: Bottle A seal broken. The MRO recommends that the agency collect another specimen from the donor. The recollected specimen must be the same type (i.e., urine).

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.1.3, pages 4-6 to 4-7; Table 4.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.5.h.

Case #19

Specimen Test Result: Invalid two times, different reasons—Negative on second observed collection.

Specimen Test Result: Invalid Result—Abnormal pH = 9.4.

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 not required to contact the MRO prior to reporting when a specimen meets the criteria for reporting as Invalid based on abnormal pH.

Discussion: The CCF includes no collector or laboratory remarks indicating a problem with the collection or the specimen. The CCF indicates that the collection was performed on a Monday in the winter and that the specimen was delivered to the laboratory early morning on the next day (Tuesday). Laboratory staff accessioned the specimen immediately upon delivery. The MRO concludes that the specimen was not exposed to high temperatures during transportation,

During the interview with the donor, the donor gives no explanation for the Invalid result. He denies having tampered with the specimen.

Conclusion: Transportation and temperature did not account for the pH in the Invalid range.

MRO Report: Test Cancelled: Invalid Result—Abnormal pH. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

Second (re-collected) Specimen Test Result: Invalid Result—Creatinine <2 mg/dL and Specific Gravity Acceptable.

Laboratory Report: 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.

Note: Laboratories are not required to contact the MRO prior to reporting when a specimen meets the criteria for reporting as Invalid based on creatinine and specific gravity.

Discussion: This is the second Invalid specimen and was collected under direct observation.

Conclusion: No legitimate explanation exists for the Invalid result. The MRO does NOT contact the donor.

MRO Report: Test Cancelled: Invalid Result—Creatinine <2 mg/dL and Specific Gravity Acceptable. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

Third (second observed) Specimen Test Result: Negative

Laboratory Report: The laboratory sent an electronic report with all required information and the testing result.

Discussion: This is the third specimen collected and the second under direct observation.

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

MRO Report: Negative.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.6.4, pages 5-10 to 5-12.

Case #20

Split Specimen Test Result: Failed to Reconfirm for Marijuana Metabolite—Reason: Invalid Result—Oxidant Activity ≥ 200 mcg/mL Nitrite Equivalents.

Laboratory B 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, including the results of specimen validity tests performed for the specimen, and was signed and dated by the certifying scientist.

Discussion: Laboratory B received the split (Bottle B) specimen from the primary laboratory with a copy of the MRO's request to test the split specimen for the marijuana metabolite (THCA), the drug metabolite that was reported positive in the primary (Bottle A) specimen. When Laboratory B was unable to reconfirm the presence of THCA, the laboratory conducted specimen validity tests to determine if there was a reason for not reconfirming the presence of THCA. Laboratory B did not identify the presence of a specific adulterant in the split specimen; however, it did find oxidant activity (i.e., ≥ 200 mcg/mL nitrite-equivalents) in the split specimen. At this point, Laboratory B contacted the MRO to decide whether additional validity testing at a third laboratory might reveal a specific adulterant. Laboratory B stated that it does not perform the tests required to report a specimen as Adulterated but performs testing only to identify the possible presence of adulterants and then report a specimen as Invalid.

After discussing the results with Laboratory B, the MRO decides to send the specimen to Laboratory C for confirmatory testing for specific oxidizing adulterants. Laboratory C finds a nitrite level above the 200-mcg/mL cutoff for an Invalid result but below the 500-mcg/mL cutoff for Adulteration and reports an Invalid result (nitrite = 350 mcg/mL) for the split (Bottle B) specimen.

Conclusion: Unlike drug analytes, because a low concentration of nitrite may be present in normal human urine, laboratories are required to use the same nitrite cutoffs (i.e., ≥ 200 mcg/mL for Invalid and ≥ 500 mcg/mL for Adulterated) for both primary (Bottle A) and split (Bottle B) specimens. Although nitrite was present in both the primary (Bottle A) specimen and the split (Bottle B) specimen, the marijuana metabolite in Bottle B may have been affected more by nitrite because more time had elapsed between collection and testing of this bottle than for Bottle A. As a result, the nitrite had additional time to act on the drug analyte. Therefore, the results for both the primary (Bottle A) and split (Bottle B) specimens are consistent.

MRO Report: Failed to Reconfirm for Marijuana Metabolite, Invalid Result—Nitrite, 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 (October 1, 2017, Rev. 0318), item 3.1.5, pages 3-3 to 3-4; item 4.5, page 4-19; item 7.2, pages 7-17 to 7-18; Appendix D, page D-5.

Case #21

Split Specimen Test Result: Failed to Reconfirm Cocaine Metabolite (BZE)—BZE not detected.

Laboratory B 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, including the results of specimen validity tests performed for the specimen, and was signed and dated by the certifying scientist.

Discussion: Laboratory B received the split (Bottle 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 (Bottle A) specimen. The copy of the Federal CCF (Copy 1) sent with the specimen documented Laboratory A's reported concentration of 10,786-ng/mL BZE. When Laboratory B was unable to reconfirm the presence of BZE, the laboratory conducted specimen validity tests to determine if there was a reason for not reconfirming the presence of BZE. Laboratory B did not identify an adulterant, the specimen was not substituted, and there was no evidence to support reporting an Invalid result.

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 (Bottle B) specimen.

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

MRO Report: 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 (October 1, 2017, Rev. 0318), item 3.1.4, page 3-3; item 3.1.5, pages 3-3 to 3-4; item 3.2, page 3-7; item 4.4, pages 4-16 to 4-17; Table 5.

Case #22

Split Specimen Test Result: Failed to Reconfirm [Chromium(VI)].

Laboratory B Report: Laboratory B sent an image of the completed Federal CCF (Copy 1) and its computer-generated electronic 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 included the electronic signature of the certifying scientist with the date that the signature was executed.

Discussion: Laboratory B received the split (Bottle B) specimen from the primary laboratory with a copy of the MRO's request to test the split specimen for Chromium(VI), which was detected (Adulterated) in the primary (Bottle A) specimen. When Laboratory B tested the split specimen, it was unable to verify the presence of Chromium(VI). At this point, Laboratory B stopped testing the split (Bottle B) specimen and reported the failed to reconfirm result to the MRO.

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

MRO Report: Failed to Reconfirm [Chromium(VI)] 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 (October 1, 2017, Rev. 0318), Appendix A, page A-2; Table 5.

Case #23

Medical Marijuana

Specimen Test Result: Positive for Marijuana Metabolite (Δ 9-THCA)—420 ng/mL.

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 a prescription 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, and no legitimate medical explanation exists for the drug test result.

MRO Report: Positive for Marijuana Metabolite.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.2, pages 5-4 to 5-5; item 7.1.2.b, page 7-6.

Case #24

Morphine Not Reported Positive

Specimen Test Result: Positive for 6-Acetylmorphine (6-AM)—17 ng/mL.

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 2000 ng/mL) in positive 6-AM specimens, morphine may not be present or may be present below 2000 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 Report: Positive for 6-AM.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.4, page 5-8; item 7.1.4, pages 7-9 to 7-14.

Case #25

Specimen Test Result: Invalid Two Times, Different Reasons; Acceptable Explanation for Abnormal pH (Transit Time/Temperature).

First Specimen Test Result: Invalid Result–Creatinine <2 mg/dL and Specific Gravity Acceptable.

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: Laboratories are not required to contact the MRO prior to reporting when a specimen meets criteria for reporting as Invalid based on creatinine and specific gravity results.*

During the interview with the donor, the donor provides no explanation for the Invalid result. She denied having tampered with the specimen. The CCF includes no collector or laboratory remarks indicating a problem with the collection or the specimen.

Conclusion: There is no apparent explanation for the Invalid result. The reason for the test was Random.

MRO Report: Test Cancelled and Remark: Invalid Result–Creatinine <2 mg/dL and Specific Gravity Acceptable. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

Second Specimen Test Result: Invalid Result–Abnormal pH = 9.4.

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: Laboratories are not required to contact the MRO prior to reporting when a specimen meets criteria for reporting as Invalid based on abnormal pH results.*

The CCF shows that the specimen collection was observed, and the female observer's name is entered in the Remarks line in Step 2. The collection time and date were 9:30 AM on July 1 (Friday). The CCF shows that the specimen was received at the laboratory on July 5 (Tuesday).

Note: The MRO does not contact the donor when the donor's second specimen also meets the criteria for reporting as Invalid.

The MRO notes the extended time (four days) between specimen collection and receipt by the laboratory. She first contacts the collector to discuss time and temperature issues. The collector informs the MRO that he had placed the sealed specimen package in refrigerated storage until 5:00 PM on Friday, awaiting pickup by a local courier. When the courier had not arrived by 5:00 PM, the collector placed this and other sealed specimen packages in a locked outside container for pickup. The collection site was closed on Monday because of the July 4 holiday. When staff arrived at the collection site on Tuesday morning, July 5, the specimens were still in the locked box. Outside temperatures over the preceding four days were in the high 90s. Collection site staff returned the sealed specimen packages to refrigerated storage and called the laboratory. A laboratory courier retrieved the specimens from the collection site at 10:45 AM.

Conclusion: The second specimen's exposure to high temperatures for an extended time may account for the high pH result in the Invalid range. The reason for the test was Random; thus, a Negative result is not required (as would be required for a federal agency applicant/pre-employment, return-to-duty, or follow-up test).

MRO Report: Test Cancelled and Remark: Invalid Result (Abnormal pH). The MRO informs the agency that no recollection is required because there is an acceptable explanation for the Invalid result.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.6.4, pages 5-10 to 5-12.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.5.f.

Case #26

Specimen Test Result: Invalid Two Times, Same Reason; Negative Result Required—Medical Evaluation

First Specimen Test Result: Invalid Result—Abnormal pH = 9.4.

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.

Discussion: *Note: Laboratories are not required to contact the MRO prior to reporting when a specimen meets the criteria for reporting as Invalid based on abnormal pH.*

The CCF includes no collector or laboratory remarks indicating a problem with the collection or the specimen. The CCF shows that the collection occurred on August 6 (Friday) and that the specimen was received at the laboratory on August 11 (Wednesday). The MRO first contacts the collector to discuss time and temperature issues. The collector states that the specimen was picked up by a commercial transporter on August 6. The MRO contacts the laboratory. Laboratory staff cannot explain the delay but state that the specimen was accessioned immediately upon delivery. The MRO concludes that the specimen may have been exposed to high temperatures during transportation, which could account for the abnormally high pH.

During the interview with the donor, the donor provides no explanation for the Invalid result. He denies having tampered with the specimen.

Conclusion: The five-day transit time may account for the Invalid result. However, because this was a return-to-duty drug test, the federal agency requires a Negative result.

MRO Report: Test Cancelled and Remark: Invalid Result (Abnormal pH). The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

Second Specimen Test Result: Invalid Result—Abnormal pH = 9.2.

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.

Discussion: The CCF shows that the specimen collection was observed. The collection occurred on August 16 (Monday), and the specimen was received at the laboratory on August 20 (Thursday).

Note: The MRO should not contact the donor when the donor's second specimen also meets the criteria for reporting as Invalid.

The MRO contacts the collector who states that the specimen was picked up by a commercial transporter on August 16. The MRO contacts laboratory staff who states that the specimen was accessioned immediately upon delivery. The MRO concludes that the specimen may have been

exposed to high temperatures during transportation, which could account for the abnormally high pH.

Conclusion: Although there is an explanation for the high pH, the federal agency requires a Negative result for a return-to-duty drug test. The MRO arranges for a medical evaluation of the donor and finds no clinical evidence of drug abuse.

MRO Report: Negative. With the report to the federal agency, the MRO provides written notations regarding the medical evaluation, an explanation of the reason for the medical evaluation, and the reason for the determination made based on the medical evaluation.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.6.4, pages 5-10 to 5-12.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.4.f.

Case #27

Collector Errors—MRO Responsibilities

Specimen Test Result: Positive for Cocaine Metabolite (BZE)—10,564 ng/mL.

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. The information on the electronic report matched the information on the Federal CCF. The Federal CCF was properly completed by the laboratory.

Discussion and MRO Report: The collector's MFR 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 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, Instrumented Initial Testing Facility [IITF], laboratory) when an error occurs more than once a month, and direct them to take corrective action to prevent recurrence of the errors.

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 (October 1, 2017, Rev. 0318), item 1.2, pages 1-4 to 1-5; item 4.1.5, pages 4-10 to 4-12.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 15.3.c.

Case #28

Specimen Test Result: Positive for Codeine—15,340 ng/mL, Morphine—4,350 ng/mL, and Oxycodone—2,320 ng/mL.

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 and morphine, the documentation provided does not support the finding of oxycodone.

MRO Report: Positive for Oxycodone.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.5.2, page 4-19; item 4.5.3, pages 4-19 to 4-21; item 5.4.1, page 5-6; item 5.4.2, pages 5-7 to 5-8.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.5.d.

Case #29

Additional Drug; Verified Negative Drug–Possible Safety Concerns

Specimen Test Result: Positive for Morphine–2,350 ng/mL.

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 morphine level measured in this case was less than 15,000 ng/mL and was likely attributable to the legitimate use of a codeine medication.

MRO Report: 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 (October 1, 2017, Rev. 0318), item 5.4.1, page 5-6; item 6.3, page 6-6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #30

Specimen Test Result: Positive for Hydromorphone—600 ng/mL and Codeine—3,350 ng/mL.

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, 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.

Conclusion: The Dilaudid prescription would justify the laboratory findings, but hydromorphone does not metabolize to codeine.

MRO Report: Negative. The donor has a valid prescription for hydromorphone, and the codeine concentration is less than 15,000 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.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 5.4.1, page 5-6; item 5.4.2, pages 5-7 to 5-8; item 6.3, page 6-6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920 (January 23, 2017), Section 13.9.d.

Case #31

Specimen Test Result: Positive for Oxycodone—2,510 ng/mL.

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 Percodan 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.

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 Report: Negative.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.5.3, pages 4-19 to 4-21; item 6.3, page 6-6.

Case #32

Specimen Test Result: Positive for Codeine—15,340 ng/mL and Morphine—2,350 ng/mL.

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. 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 and morphine that specifies no time limitations on the use of the drug (even if the expiration date on the dispensed prescription has expired).

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 Report: Negative for morphine and codeine.

References:

HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (October 1, 2017, Rev. 0318), item 4.5.3, pages 4-19 to 4-21; item 5.4.1, page 5-6; item 6.3, page 6-6.

Mandatory Guidelines for Federal Workplace Drug Testing Programs, 82 Fed. Reg. 7920
(January 23, 2017), Section 13.9.d.