2010 Medical Review Officer (MRO) Case Studies

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Specimen Test Result: Positive for Marijuana Metabolite (Δ9-THCA) - 30 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 except that 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 MRO must discuss the positive test result with the donor. During the donor interview, the donor claims he was positive because of passive inhalation. He states that he was at a party on Saturday night in which several individuals were smoking marijuana, but he did not smoke a joint. The Federal CCF documents that the donor's specimen was collected 2 days after the claimed passive exposure occurred.

Conclusion: Clinical studies have shown that it is highly unlikely that a non-smoking individual could unknowingly inhale sufficient smoke by passive inhalation to result in a high enough drug concentration in urine for detection at the cutoff concentrations used in the Federal agency program. In this case, the circumstances described by the donor do not approximate what would be needed to explain the presence of the marijuana metabolite in the donor's urine by passive inhalation.

MRO Report: Positive for Marijuana

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.

MRO Report: Negative

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.

MRO Report: Negative

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 (currently and at the time of the drug test) he is taking a prescription medication that contains codeine (i.e., Tylenol with Codeine). 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. However, if the MRO believes that the medication could impact on the occupational and safety aspects associated with the donor's job, the MRO must decide what must be done with the information. The MRO must preserve the confidentiality of the medical information by providing the information on a strict "needto-know" basis. Unless required by regulation or law, the MRO must only discuss specific medical information with another physician or qualified health professional. It is recommended that the MRO contact the prescribing physician to discuss the possible impact that the medication may have on the safety aspects of the work performed by the donor. In addition, some occupations may have restrictions that prohibit an individual from taking specific medications. In these instances, the MRO may inform the individual responsible for certifying that the donor is qualified to perform that job that the donor is taking one of the restricted medications.

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 he states that he had used some over-the-counter decongestants and used 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 the laboratory to perform a chiral analysis to determine which enantiomers of methamphetamine are in the specimen. Since *I*-methamphetamine is a legitimate component of some over-the-counter (OTC) nasal decongestant products, including the Vicks® VapoInhaler®, the MRO wants to be certain that the reported methamphetamine did not come from using the Vicks® VapoInhaler®. The laboratory reports that approximately 90 percent of the methamphetamine is the *d*-enantiomer. Since a Vicks® VapoInhaler® contains *I*-methamphetamine (listed in ingredients as levmetamfetamine), the *d*-methamphetamine could not come from this OTC product.

Conclusion: The donor used a prescription medication illegally or used an illegal source of methamphetamine. In either case, there is no valid medical explanation for the positive result.

MRO Report: Positive for Methamphetamine

Specimen Test Result: Positive for Cocaine Metabolite (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 the 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, it was used 10 days before the urine specimen was collected.

Conclusion: Because the documented use of cocaine was 10 days before the drug test, the positive result could not have resulted from this medical use of cocaine. Generally, the detection window for the cocaine metabolite in urine is 2 to 3 days after use when using the cutoff concentrations required for testing federally regulated specimens.

MRO Report: Positive for Cocaine

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 Percodan® (oxycodone and aspirin) at the time that he submitted a urine specimen. The donor also states that he routinely eats poppy seed bagels.

The MRO requests the donor to provide evidence of a valid prescription. The donor brings a prescription bottle showing legitimate Percodan® use at the time of the drug test, with no refills allowed.

Note: If refills had been allowed, the MRO must contact the prescribing physician to express concern that the continued use of the medication may present a significant safety problem for the donor. Because oxycodone is a drug with a high potential for abuse, there must be appropriate documentation for its long term use.

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, Percodan® cannot cause a urine specimen to test positive for morphine or codeine because oxycodone does not metabolize to morphine or codeine. Since the donor had used the Percodan® according to the physician's instructions and had stopped using the medication 3 days after the drug test, there is no reason to contact the prescribing physician to discuss the donor's continued use of a medication that may have an impact on occupational and public safety. However, the MRO should inform the donor that taking any remaining Percodan® tablets after its intended use as prescribed by his physician is considered illegal and to caution him regarding the possible side effects if the Percodan® tablets are taken.

MRO Report: Negative

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 concentration of the methamphetamine is significantly higher than the amphetamine concentration, it appears that the amphetamine is 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 Vicks® VapoInhaler® 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 if the methamphetamine came from Vicks® VapoInhaler® use, the MRO requests the laboratory to perform a chiral analysis. The results show that over 95 percent of the methamphetamine and amphetamine present in the urine were the *I*-enantiomers.

The MRO requests the donor to bring him a copy of his medical record. The record shows legitimate prescription use of the Valium®.

Conclusion: The chiral analysis supports the use of an over-the-counter Vicks® VapoInhaler® as the reason for the positive drug test result. Although the workplace drug testing program does not test for benzodiazepines (e.g., Valium®), the MRO has been given information by the donor that could potentially impact on the donor's safety or on public safety. The MRO should contact the prescribing physician to determine if the warnings associated with Valium® use have been discussed with the donor and taken into consideration with regard to dosage and possible side effects.

MRO Report: Negative. The legitimate use of Valium® is confidential medical information and may not be given to the agency unless its use is specifically prohibited by an applicable regulation in the agency's drug testing regulation. If it is specifically prohibited, the MRO informs the individual responsible for certifying the donor to perform that job that the donor is taking a restricted medication.

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 has taken Adipex-P® (phentermine) for weight control, has taken a free sample given to him by his physician (but he cannot remember the name of the sample), frequently uses a Vicks® VapoInhaler® for a stuffy nose, and uses a number of 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 HCI) 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 Vicks® VapoInhaler® does contain *I*-methamphetamine.

To determine whether the Vicks® VapoInhaler® caused the positive result, the MRO requests the laboratory to conduct a chiral analysis. The laboratory reports the following results: 37 percent *d*-methamphetamine and 63 percent *l*- methamphetamine.

Conclusion: Neither Tenuate® nor Adipex-P® were 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 Vicks® VapoInhaler® were the only source of methamphetamine in this urine, the percentage of *I*-methamphetamine would have been greater than 80 percent. The donor clearly ingested another source of methamphetamine containing the *d*-isomer.

MRO Report: Positive for Methamphetamine

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 does not have a legitimate explanation to explain the presence of nitrite.

MRO Report: Refusal to Test because Adulterated - Nitrite = 850 mcg/mL

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

Laboratory Report: Before reporting an invalid result to the MRO for this reason, the laboratory must attempt to contact the MRO to decide whether additional testing at a different laboratory would be useful to obtain a definitive result. In this case, the laboratory and MRO have discussed the result and agreed that additional testing is not necessary. 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: During the interview with the donor, the donor claims to have no idea how an oxidant could be in his or her urine specimen.

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

MRO Report: Test Cancelled and Remark: Invalid Result – Oxidant Activity ≥50 mcg/mL Chromium (VI)-equivalents. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

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 a different physical appearance 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, it is recommended that the MRO report only the adulterated result to the agency. Reporting both the Refusal to Test (Adulterated) and Test Cancelled (Invalid Result) at the same time on a 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.

MRO Report: Refusal to Test because Adulterated – Nitrite = 1800 mcg/mL

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.

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 adulterated.

Conclusion: The concentration of morphine in the urine specimen is consistent with eating poppy seeds. During the interview, the MRO is satisfied that there is no clinical evidence of opiate abuse. Therefore, the morphine drug test result would be reported as negative. For the adulterated result, there is no legitimate medical explanation for the presence of a highly toxic oxidant in a urine specimen.

MRO Report: Refusal to Test because Adulterated – Chromium (VI) = 90 mcg/mL

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 was positive for marijuana because he was at a party and had eaten brownies that contained marijuana and that he was positive for cocaine because a dentist had used lidocaine prior to a dental procedure. The Federal CCF documents that the donor's specimen was collected 3 days after he claimed eating the brownies and one day after the dental procedure.

Conclusion: Unknowing ingestion of marijuana in brownies has been claimed by donors for many years as the reason for a positive test result. It is highly unlikely that the amount of the marijuana metabolite in a urine specimen following unknowing ingestion would exceed the cutoff concentrations used in the Federal workplace drug testing program. In this case, the circumstances described by the donor do not approximate what would be needed to explain the presence of the marijuana metabolite in the donor's urine. With regard to the cocaine metabolite, lidocaine does not contain cocaine and does not metabolize to the cocaine metabolite.

MRO Report: Positive for Marijuana and Cocaine

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 value of normal human urine. When the 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 requests the agency to have the donor provide another urine specimen using a direct observed collection procedure and to have the collector document that the donor drank a similar quantity of fluids prior to providing the specimen. The MRO does not report the final result to the agency until the laboratory reports the test result for the second specimen.

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 the results for the first specimen. Therefore, the donor's explanation that he drank large quantities of fluids prior to the first test was not a legitimate explanation for the Substituted result.

MRO Report: Refusal to Test because Substituted

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 possibly indicates that a donor may have intentionally consumed large amounts of fluid or had taken diuretics in an attempt to reduce any drug concentrations to test below the cutoffs used, but not necessarily. A donor could provide a dilute specimen in other situations (e.g., because the donor drank fluid to provide a specimen when required at the collection site).

MRO Report: Negative and Dilute. The MRO directs the agency to <u>immediately</u> collect another specimen from the donor (i.e., notify the donor to report to the collection site without delay). The second collection is <u>not</u> 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 second specimen is also dilute, the MRO should contact the donor to discuss possible reasons for the dilute finding.

Conclusion: A second dilute finding possibly indicates that a donor may 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, or drinking fluids immediately before providing the specimen or because the donor drank fluid to provide a specimen when required at the collection site. The MRO should contact the donor to determine whether the donor can explain the reason for the two dilute findings:

- If the donor documents a medical reason for the dilute urine (e.g., a valid prescription for a diuretic), the MRO reports a negative result to the agency.
- If there is no apparent reason for the dilute findings or if the donor claims that he or she drank fluid prior to or during the collection in order to provide a sufficient specimen, the MRO instructs the donor to refrain from consuming excessive fluids prior to and during the next collection.
- The MRO directs the agency to <u>immediately</u> collect another specimen from the donor (i.e., notify the donor to report to the collection site without delay). The agency should also instruct the donor to refrain from consuming excessive fluids

prior to and during the collection. The collection is <u>not</u> to be a direct observed collection.

Third Collection Specimen Test Result: Negative

Conclusion: The MRO reports a negative result to the agency and informs the agency that they may, but are not required to, use a direct observed collection procedure the next time the donor is selected for a drug test.

Note: DOT requires an immediate collection of a second specimen using a direct observed collection procedure when the creatinine concentration for a negative-dilute specimen is between 2.0 and 5.0 mg/dL. Reference: 49 CFR Part 40; Procedures for Transportation Workplace Drug and Alcohol Testing Programs; 40.155(c)

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 immediately collecting a second specimen using a direct observed collection procedure. To avoid confusion, it is not unreasonable to 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. While both a failure to reconfirm and an invalid result lead to a cancelled test and immediate recollection using direct observation, the MRO will have invalid result information for the first specimen for review when he/she reviews the recollected specimen's test results.

MRO Report: Refusal to Test because Substituted

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 HHS 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. When a correctable flaw is identified, the laboratory usually proceeds with testing the specimen but can not report the test results unless the flaw is recovered (e.g., by a memorandum for the record (MFR) from the collector). A laboratory may choose to delay testing the specimen until the collector provides the documentation to recover a correctable flaw.

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 this 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 informs the MRO that a split specimen is not available.

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

MRO Report: TEST CANCELLED and Remark: Fatal Flaw: Bottle A seal broken. The MRO directs the agency to immediately collect another specimen

Split Specimen Test Result: Failed to Reconfirm Benzoylecgonine – Reason: Adulterated - pH = 11.5)

Laboratory B Report: Lab B faxed a copy of the completed Federal CCF (Copy 1) and its Split Specimen Report for the specimen. Lab 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: Lab B received the split (Bottle B) specimen from the primary laboratory with a copy of the MRO request to test the split specimen for benzoylecgonine, the drug metabolite that was reported positive in the primary (Bottle A) specimen. When Lab B was unable to reconfirm the presence of benzoylecgonine, the laboratory conducted specimen validity tests to determine if there was a reason for not reconfirming the presence of the benzoylecgonine. Lab B determined and reported that the pH of the split (Bottle B) specimen was in the adulterated range.

After the adulterated result is reported to the MRO, the donor immediately requests that Lab A retest Bottle A to determine its pH. Lab A reports that the pH of Bottle A is 8.2, which is in the acceptable range (i.e., not adulterated).

Conclusion: The high pH of the split (Bottle B) specimen explains the failure to reconfirm benzoylecgonine.

MRO Report: Failed to Reconfirm for Benzoylecgonine 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. The MRO notifies the appropriate regulatory office about the failed to reconfirm and cancelled test.

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

Laboratory B Report: Lab B faxed a copy of the completed Federal CCF (Copy 1) and its Split Specimen Report for the specimen. Lab 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: Lab 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 Lab 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 the THCA. Lab B did not identify the presence of a specific adulterant in the split specimen; however, it was able to determine that there was oxidant activity (i.e., \geq 200 mcg/mL nitrite-equivalents) in the split specimen. At this point, Lab B contacts the MRO to decide whether additional validity testing at a third laboratory would be able to identify a specific adulterant. Lab 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 Lab B, the MRO decides to send the specimen to Lab C for confirmatory testing for specific oxidizing adulterants. Lab C identifies nitrite 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., $\geq 200 \text{ mcg/mL}$ for invalid and $\geq 500 \text{ mcg/mL}$ for adulterated) for both primary (Bottle A) and split (Bottle B) specimens. While 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 the A Bottle. This allowed additional time for the nitrite 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 and Remark: Invalid Result - Nitrite = 350 mcg/mL, 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.

Note: DOT does not require Lab B to discuss possible additional testing with the MRO. Lab B decides whether to send the specimen to Lab C for additional testing. Ref: 49 CFR Part 40; Procedures for Transportation Workplace Drug and Alcohol Testing Programs; 40.177(d) and 40.179(b)

Split Specimen Test Result: Failed to Reconfirm Benzoylecgonine - Reason: Benzoylecgonine Not Detected

Laboratory B Report: Lab B faxed a copy of the completed Federal CCF (Copy 1) and its Split Specimen Report for the specimen. Lab 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: Lab 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 benzoylecgonine, the drug metabolite that was reported positive in the primary (Bottle A) specimen. The copy of the Federal CCF (Copy 1) sent with the specimen documented Lab A's reported concentration of 10,786 ng/mL benzoylecgonine. When Lab B was unable to reconfirm the presence of benzoylecgonine, to the laboratory conducted specimen validity tests to determine if there was a reason for not reconfirming the presence of benzoylecgonine. Lab B did not identify an adulterant, the specimen was not substituted, and there was no evidence to report an invalid result.

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

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

MRO Report: Failed to Reconfirm for Benzoylecgonine 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: DOT does not require Lab B to discuss possible additional testing with the MRO. Lab B decides whether to send the specimen to Lab C for additional testing. Ref: 49 CFR Part 40; Procedures for Transportation Workplace Drug and Alcohol Testing Programs; 40.177(d) and 40.179(b)

Split Specimen Test Result: Failed to Reconfirm; Not Adulterated - Reason: Chromium (VI) not present

Laboratory B Report: Lab B sent an image of the completed Federal CCF (Copy 1) and its computer-generated electronic Split Specimen Report for the specimen. Lab 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: Lab 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) that was reported present (adulterated) in the primary (Bottle A) specimen. When Lab B tested the split specimen, it was unable to verify the presence of Chromium (VI). At this point, Lab 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 results for the primary (Bottle A) and split (Bottle B) specimens.

MRO Report: Failed to Reconfirm for Chromium (VI) - Not Adulterated 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.

NEW!

Case #23 Medical Marijuana

Specimen Test Result: Positive for Marijuana Metabolite (Δ9-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), 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. There are no legitimate medical reasons for anyone to use drugs listed in Schedule I of the Controlled Substance Act, and there are no legitimate medical reasons for physicians (and others) to recommend Schedule I drugs for use.

MRO Report: Positive for Marijuana

NEW! **Case #24 6-AM positive, morphine negative**

Specimen Test Result: Positive for 6-Acetylmorphine – 17 ng/mL and morphine is not reported positive

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 notifies the MRO that the opiates initial test was negative, so an opiates confirmatory test had not been performed. The MRO sends a written request to the laboratory to test the specimen to obtain the quantitative results for other opiates (codeine and morphine) using its opiates confirmatory analysis. It is acceptable for the MRO to request this analysis to provide the additional interpretive information for the 6-acetylmorphine result. The certifying scientist annotates the comment "codeine present" and the morphine concentration of 1075 ng/mL in the Remarks line of the Federal CCF and on any resent electronic report. The presence of morphine is consistent with the positive 6-acetylmorphine result.

During the interview with the donor, the donor denies heroin use. The MRO does not find any clinical evidence of abuse of opiates.

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

MRO Report: Positive for 6-Acetylmorphine

NEW!

Case #25 Invalid 2 times, different reasons (transit time/temperature)

1st **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 has no explanation for the invalid result. She denies having tampered with the specimen. There are no collector Remarks or laboratory Remarks on the CCF indicating a problem with the collection or the specimen.

Conclusion: There is no apparent explanation for the invalid result. The reason for 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.

2nd 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 collector Remarks line. The collection time and date was 9:30 AM on July 1 (Friday). The CCF shows 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 criteria for reporting as invalid.

The MRO notes the extended time (4 days) between the 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, due to the July 4th 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 4 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 accounts for the high pH result in the invalid range. The reason for test was random, so a negative test 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 = 9.4. The MRO directs the agency that a recollection is not required because there is an acceptable explanation for the invalid result.

NEW!

Case #26 Invalid 2 times, same reason (transit time/temperature); negative result required – medical evaluation

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 <u>not</u> required to contact the MRO prior to reporting when a specimen meets criteria for reporting as invalid based on abnormal pH.

There are no collector Remarks or laboratory Remarks on the CCF indicating a problem with the collection or the specimen. The CCF shows that the collection was on August 6 (Friday) and receipt at the laboratory was 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 has no explanation for the invalid result. He denies having tampered with the specimen.

Conclusion: The 5-day transit time may account for the invalid result. However, because this is a return to duty drug test, the Federal agency requires a negative result.

MRO Report: TEST CANCELLED and Remark: Invalid Result –Abnormal pH = 9.4. The MRO directs the agency to immediately collect another specimen using a direct observed collection procedure.

2nd 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 was on August 16 (Monday) and the specimen was received at the laboratory on August 20 (Thursday).

Note: The MRO does not contact the donor when the donor's second specimen also meets 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 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.

Conclusion: Although there is an explanation for the high pH, the Federal agency requires a negative report 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 that was made based on the medical evaluation.

NEW! 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 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 monitors the frequency of documentation errors and notifies the responsible party (e.g., collector, IITF, laboratory) when an error has occurred more than once a month, directing them to take corrective action to prevent recurrence of the errors.

Additional MRO actions: The MRO sends a letter notifying the collector employer or collector (if self-employed) of the errors and the need for corrective action. The MRO sends a copy of the letter to the Federal agency for follow-up.