

Subpart G - Medical Review Officers and the Verification Process

§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive test for a drug or drug metabolite, unless the creatinine concentration for a substituted specimen was reported by the laboratory to be equal to or more than 2 mg/dL.

(1) If the laboratory has reported the creatinine concentration for a substituted specimen as equal to or more than 2 mg/dL, you must report the specimen to the DER as being dilute, as provided in §40.155 of this part. Notwithstanding any other provision of this part, you must also instruct the DER that a second collection under direct observation must take place immediately.

(2) If the laboratory has reported the creatinine concentration for a substituted specimen as less than 2 mg/dL or "creatinine not detected," you must follow the procedures set forth in paragraphs (b) through (h) of this section.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see §§40.129–40.135, 40.141, 40.151), except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine, through physiological means, meeting criteria for creatinine of less than 2 mg/dL and for specific gravity of less than or equal to 1.001 or greater than or equal to 1.020.

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the "referral physician"), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

(B) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether there is a legitimate medical explanation. Any additional urine tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (e.g., referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of §40.93(b) .

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (e.g., with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of §40.93(b) .

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of §40.93(b) .

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of §40.93(b) .

[65 FR 79526, Dec. 19, 2000, as amended at 68 FR 31626, May 28, 2003]