

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1051673	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Och Evergreen Clinic	Street Address, City, State 1540 E Evergreen St, Springfield, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency records for 2023 and interview with the technical consultant (TC), the laboratory failed to establish a means to verify the accuracy of 12 of 12 analytes twice yearly. Findings: 1. Review of proficiency records for 2023 showed the laboratory failed to prove accuracy on the non-regulated analytes: marijuana (THC), phencyclidine (PCP), cocaine (COC), opiates (OPI), amphetamine (AMP), methamphetamine (MAMP), benzodiazepine (BZO), tricyclic antidepressant (TSA), methadone (MTD), barbiturates (BAR), oxycodone (OXY) and buprenorphine (BUP) twice yearly. 2. Interview with the TC on October 17, 2023 at 10:30 AM confirmed the laboratory failed to verify the accuracy of 12 non-regulated analytes twice annually.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Medtox analyzer verification procedures, lab director qualifications, testing personnel training, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to ensure the required documentation to</p>

qualify the individual serving as laboratory director (Refer to D6003); the LD failed to ensure verification procedures are adequate to determine the accuracy, precision and other pertinent performance characteristics for the Medtox analyzer (Refer to D6013); and the LD failed to ensure three testing personnel (TP) had appropriate training for moderate complexity testing prior to testing and reporting patient results (Refer to D6029).

D6003

LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic

Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the technical consultant, the laboratory failed to have documentation to show the laboratory director obtained at least one year of laboratory training or experience, or both, in moderate complexity testing. Findings: 1. The laboratory failed to have documentation to show the laboratory director obtained the required laboratory training and/or experience for the position of laboratory director. The current laboratory director started on September 30, 2023. 2. Interview with the technical consultant on October 17, 2023 at 10:30 AM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as laboratory director.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on review of the Medtox toxicology analyzer verification procedures and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure verification procedures are adequate to determine the accuracy, precision, reportable range and to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. for the Medtox toxicology analyzer. Findings: 1. Review of the Medtox toxicology analyzer verification procedures showed no accuracy, precision, reportable range and to verify that the manufacturer's reference intervals (normal values) for the analytes: marijuana (THC), phencyclidine (PCP), cocaine (COC), opiates (OPI), amphetamine (AMP), methamphetamine (MAMP), benzodiazepine (BZO), tricyclic antidepressant (TSA), methadone (MTD), barbiturates (BAR), oxycodone (OXY) and buprenorphine (BUP). The laboratory performed 4320 toxicology tests from February 2023 to date October 17, 2023. 2. Interview with the TC on October 17, 2023 at 9:30 AM confirmed, the LD failed to ensure verification procedures are adequate to determine the accuracy, precision, reportable range, and normal values for the Medtox toxicology analyzer.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Review of personnel training records for 2023 and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure three of three testing personnel (TP) had appropriate training for moderate complexity testing prior to testing and reporting patient results. Findings: 1. Review of training documentation for 2023 revealed the director failed to have initial training for TP #1, TP #2, and TP #3 who started testing February 2023. The laboratory performed 4320 toxicology tests from February 2023 to date October 17, 2023. 2. Interview with the TC on October 17, 2023 at 10:00 AM confirmed, the LD failed to ensure TP had appropriate training for moderate complexity testing before testing patient specimens.