Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2166918	08/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pain Management Of Oklahoma, Pllc	1201 E Wade Watts Ave, Mcalester, OK	

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
D0000	The recertification survey was performed on 08/02/2023. The laboratory was found out of compliance with the following CLIA Conditions: 493.1441; D6076: Laboratory Director, High Complexity Testing 493.1487; D6168: Testing Personnel, High Complexity Testing The findings were reviewed with the laboratory director and Trinity consultant at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory director, the laboratory failed to have a written policy to assess the competency of the clinical consultants, based on the position responsibilities as listed in Subpart M, for two of two persons. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the clinical consultants, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of December 2020 through the current date identified competencies, based on job responsibilities, had not been performed for two of two persons listed as clinical consultant on Form CMS-209 since 12/10/2020; (3) The findings were reviewed with the laboratory director who stated on 08/01/2023 at 10:30 am the laboratory did not have a policy and competencies had not been performed for the clinical consultants since 12/10/2020.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person performing testing from October 2021 through the current date. Findings include: (1) A review of personnel records for one person performing moderate complexity testing since October 2021 identified the following for one of one person: (a) Testing Person #3 - The initial training was complete on 10/20/2021. There was no evidence an evaluation had been performed between 10/20/2021 and 12/28/2022. (2) The records were reviewed with the laboratory director who stated on 08/02/2023 at 11:09 am, a semiannual competency evaluation had not been performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, FDA database, and interview with the laboratory director, the laboratory director failed to meet the qualification requirements for high complexity testing. Findings include: (1) The laboratory performed high complexity pH, Specific Gravity, and Oxidant testing using the Siemens Viva Pro-E analyzer and the laboratory director did not meet the regulatory qualifications for high complexity testing. Refer to D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; 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 and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, patient and interview with the laboratory director, the laboratory director failed to ensure the laboratory director met the regulatory qualifications for pH, Specific Gravity, and Oxidant testing using the Siemens Viva Pro-E which was not cleared or approved by the FDA. Findings include: (1) On 08/02/2023 at 09:30 am, the laboratory director stated the following: (a) Urine Drug Screen (Amphetamine, Benzodiazepines, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone) pH, Specific Gravity, and Oxidant testing were performed using the Siemens Viva Pro-E analyzer; (b) pH, Specific Gravity, and Oxidant testing were used to determined the acceptability of the sample for Urine Drug testing. (2) A review of five patient reports (testing performed on 02/03/2023, 03 /09/2023, 04/25/2023, 05/08/2023, 07/12/2023) identified the laboratory reported the results for the pH, Specific Gravity, and Oxidant testing; (3) A review of the manufacturer's package insert for the above testing, under "Intended Use" stated, "This test is for forensic/toxicology use only"; (4) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the tests (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (5) A review of the laboratory director credentials identified the laboratory director did not meet the regulatory qualifications for a high complexity laboratory director; (6) The findings were reviewed with the laboratory director who stated on 08/02/2023 at 11:30 am, the pH, Specific Gravity, and Oxidant testing were included on the patient report and they were not aware the tests had not been FDA approved.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure two of three testing persons met the qualification requirements to perform high complexity testing. Findings include: (1) The laboratory failed to ensure

	that each person performing high complexity pH, Specific Gravity, and Oxidant testing met the qualification requirements. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have

	earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the laboratory director, the laboratory failed to ensure that each person performing high complexity testing met the qualification requirements for two of three persons listed on the CMS-209. Findings include: (1) On 08/02/2023 at 09:30 am, the laboratory director stated the following: (a) Urine Drug Screen (Amphetamine, Benzodiazepines, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone) pH, Specific Gravity, and Oxidant testing were performed using the Siemens Viva Pro-E analyzer; (b) pH, Specific Gravity, and Oxidant testing were used to determined the acceptability of the sample for Urine Drug testing. (2) A review of five patient reports (testing performed on 02/03/2023, 03/09/2023, 04/25/2023, 05/08/2023, 07/12/2023) identified the laboratory reported the results for the pH, Specific Gravity, and Oxidant testing (3) A review of the manufacturer's package insert for the above testing, under "Intended Use" stated, "This test is for forensic/toxicology use only"; (4) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the tests (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (5) A review of the Laboratory Personnel Report (Form CMS-209) and education records for three testing persons identified two of three testing persons did not meet the qualification requirements to perform high complexity testing; (6) The findings were reviewed with the laboratory director who stated on 08/02/2023 at 11: 30 am, the pH, Specific Gravity, and Oxidant testing were included on the patient report and they were not aware the tests had not been FDA approved.