Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2166918	**(X3) Date Survey Completed** 08/14/2025
Name of Provider or Supplier Pain Management Of Oklahoma, Pllc	**Street Address, City, State** 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 08/14/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, quality assurance manager, and technical manager at the conclusion of the survey.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, QA (quality assurance) manager, and technical manager, the laboratory failed to verify the accuracy of Urine Drug Screen testing at least twice annually during the review period of August 2023 through the current date. Findings include: (1) On 08/14/2025 at 09: 50 am, the laboratory director stated the following: (a) The laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, Oxycodone using the Siemens Healthineers Viva-ProE analyzer; (b) The laboratory enrolled and participated in a proficiency testing program to meet the twice annually accuracy verification requirement. (2) A review of records from August 2023 through the current date identified the following: (a) No evidence the laboratory had participated in proficiency testing during the second 2023 event for the analyte Methadone; (b) No evidence the laboratory had participated in proficiency testing during the second 2024 event for all analytes. (3) Interview with the laboratory director on 8/14/2025 at 10:30 am confirmed Urine Drug Screen had not been verified for accuracy at least twice annually in 2023 and 2024 as indicated above.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of policy, direct observation, and interview with the technical consultant, the laboratory failed to follow their policy for specimen labeling for four of four patient samples observed. Findings include: 1. On 08/14/2025 at 11:00 am a review of the policy, "Specimen Collection, Rejection and transport" stated, "Place the following information on the bottle label:"; (a) Date of collection; (b) Donor's name and/or identification numbers; (c) Collector's initials. 2. Direct observation of the lab on 08/14/2025 at 11:00 am, revealed four patient samples labeled with a patient's first and last name and date of birth; 3. Interview with the technical consultant at 11:00 am on 08/14/2025, confirmed the laboratory failed to follow their policy for specimen identification and integrity.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, QA (quality assurance) manager and technical manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Siemens Healthineers Viva-ProE analyzer during the review period of August 2024 through July 2025. Findings include: (1) On 08/14/2025 at 09:50 am, the laboratory director stated the laboratory performed urine drug testing (Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, Oxycodone) using the Siemens Healthineers Viva-ProE analyzer; (2) A review of the operator's manual titled "Viva-ProE System Operator's Guide" under section 7.1.3 "Maintenance Checklist" showed the following required maintenance procedures: (a) Daily: (i) Check reagent rotor compartment (b) Weekly (i) Perform probe rinse procedure (c) Monthly: (i) Clean treated water and waste containers (ii) Clean instrument exterior (iii) Clean reagent rotor compartment (iv) Check/fill cooling fluid (d) Quarterly: (i) Replace drying block (e) Semi-annual: (i) Replace stirrer bell (ii) Replace water filter (iii) System clean (3) A review of maintenance records from August 2024 through July 2025 identified daily, weekly, monthly, and quarterly maintenance had not been documented as performed as follows: (a) Daily: (i) Not documented as performed during the review period (b) Weekly: (i) Between 11/25/2024 and 04/05/2025 (c) Monthly: (i) Between 11/06/2024 and 05/14/2025 (Clean treated water and waste containers not performed) (ii) Prior to 09/23/2024 (Clean instrument exterior not performed, clean reagent rotor compartment not performed, and fill cooling fluid not performed) (iii) Between 09/23/2024 and 04/25/2025 (Clean instrument exterior not performed, and clean reagent rotor compartment not performed) (iv) Between 10/28 /2024 and 04/11/2025 (Fill cooling fluid not performed) (d) Quarterly: (i) Between 09 /04/2024 and 05/02/2025 (e) Semi-annual (i) After 10/24/2024 (Replace water filter

	not performed) (ii) System clean procedure - Not documented as performed during the review period (4) Interview with the laboratory director, QA manager, and technical manager on 08/14/2025 at 12:20 pm confirmed the maintenance procedures had not been documented as performed as stated above.