Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2166918	03/25/2021
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 initial survey was performed on 03/25/2021. The findings were reviewed with the laboratory manager and laboratory director at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 a review of records, written policies, and interview with the laboratory manager, the laboratory failed to follow their written quality control policy for 4 of 4 lot numbers. Findings include: (1) On 03/25/2021, the surveyor reviewed the written policy titled "New Lot Verification". It stated the following: (a) "QUALITATIVE REAGENTS: For qualitative non-waived tests, minimum cross-checking includes retesting at least one positive, one low or weakly positive, and one negative sample with know reactivity against the new reagent lot."; (2) The surveyor reviewed 2020 new reagent lot verification records for the Siemens Viva E analyzer and identified that the laboratory had not followed their policy for lot verification for 4 of 4 lot numbers as follows: (a) UTAK Positive Contol Lot# C4417 put into use on 04/10 /2020 (b) UTAK Negative Contol Lot# C3963 put into use on 06/30/2020 (c) UTAK Negative Control Lot# C4786 put into use on 06/03/2020 (d) UTAK Positive Contol Lot# C4269 put into use on 06/30/2020 (3) The findings were reviewed with the laboratory manager, who stated on 03/25/2021 at 03:50 pm the laboratory had not followed their policy for new lot verification as indicated above.
D5429	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 3 of 4 months. Findings include: (1) On 03/25 /2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed qualitative Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone testing for urine specimens on the Viva Pro E analyzer. (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) F10 Exit the Viva-E program and perform a Windows computer Restart, Start Viva-E program; (b) Perform needle rinse cleaning procedure; (c) Check the syringes for large air gaps. Fill system several times or if necessary replace the syringes. (3) The surveyor then reviewed maintenance records for 4 months (August 2019 through November 2019). There was no evidence the weekly maintenance had been performed: (a) Between 08 /07/2019 and 08/30/2019 (b) Between 09/16/2019 and 09/26/2019 (c) Between 10/16 /2019 and 11/08/2019 (d) Between 05/30/2021 and 06/17/2021 (4) The surveyor reviewed the records with the laboratory manager, who stated on 03/25/21 at 02:00 pm, the weekly maintenance had not been performed as required.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the

	laboratory failed to perform calibration verification procedures at least once every 6 months for the analytes performed on the Siemens Viva-Jr analyzer for 2 of 12 months. Findings include: (1) On 03/25/2021 at 09:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed qualitative Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone testing for urine specimens on the Viva Pro E analyzer; (2) The surveyor reviewed 2020 calibration records with the laboratory manager, and identified calibration procedures had not been performed with calibration materials that included a low, mid, and high value as required every six months during the review period; (3) The surveyor then reviewed the records with the laboratory manager, who stated on 03/25/2021 at 01:15 pm, calibration verification procedures had not been performed in 2020 as indicated above.