Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2174534	08/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pmo Medical, Pllc	204a S Grand St, Grove, 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 08/11/2021. The findings were reviewed with the laboratory supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 supervisor, the laboratory failed to ensure the accuracy of testing was verified at least twice annually. Findings include: (1) On 08/11/2021 at 11:00 am, the laboratory supervisor stated to the surveyor the laboratory began performing urine drug testing (Amphetamines, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiates, Oxycodone, Oxidant, pH, Specific Gravity) using the Viva Pro E analyzer on 01/23 /2020; (2) The surveyor reviewed records for testing performed in 2020 and identified the accuracy of the specific gravity and oxidant testing had not been verified twice annually during the review period; (3) The surveyor reviewed the records with the laboratory supervisor, who stated on 08/11/2021 at 11:15 am, the accuracy of urine drug testing had not been verified twice in 2020 as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure control materials were not used beyond the manufacturer's open vial stability for 3 of 3 months. Findings include: (1) On 08/11/2021 at 11:00 am, the laboratory supervisor stated the following to the surveyor: (a) The laboratory performed qualitative urine drug testing on the Vivo Pro E analyzer for the analytes Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone; (b) The laboratory performed quantitative Oxidant, Specific Gravity, and pH testing for urine specimens on the Viva Pro E analyzer; (c) Two levels of Siemens Emit quality control materials were performed each day of patient testing. (2) The surveyor reviewed the manufacturer's information sheet for the control materials. Under the section, "Stability" the manufacturer stated, " Once opened, the Emit calibrators/Controls are stable for 5 weeks when recapped and stored at 2-8C when not in use."; (3) The surveyor reviewed quality control records for 2 lot numbers of quality control materials used from 05/20/2021 through the day of the survey (08/11/2021). It was identified controls had been used beyond the manufacturer's open vial stability date for 2 of 2 lot numbers reviewed as follows: (a) Level 0 (negative control) - Lot# 9A508UL-N4 had an open date of 06/22/2021 (written on the bottle and observed by the surveyor at 01:30 pm); (1) The quality control material was available for use beyond the manufacturer's open vial stability of 07/27/2021; (b) Level 5 (positive control) - Lot# 9A608LU-N5 had an open date 05/20 /2021 (written on the bottle and observed by the surveyor at 01:30 pm); (1) The quality control material was available for use beyond the manufacturer's open vial stability of 06/24/2021. (4) The surveyor reviewed the records with the laboratory supervisor, who stated on 08/11/2021 at 01:41 pm the controls had been used beyond the manufacturer's stability date as indicated above; (5) The surveyor reviewed patient testing records and identified that urine drug testing had been performed when the laboratory used quality control materials beyond the manufacturer's stability to assess the acceptable performance of the analyzer on 06/29/2021 at 10:58 am, 06/30/2021 at 03:15 pm, 07/01/2021 at 11:05 am, 07/28/2021 at 10:31 am, 07/27/2021 at 01:45 pm, 07/29/2021 at 1045 am, 08/10/2021 at 12:46 pm, and 08/11/2021 at 10:11 am.
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 supervisor, the laboratory failed to perform calibration verification procedures at least once every 6 months for the analytes performed on the Viva Pro E analyzer for 2 of 12 months. Findings include: (1) On 08/11/2021 at 11:00 am, the laboratory supervisor stated to the surveyor an 11-panel urine drug screen (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiates, Oxycodone, Oxidant, pH, and Specific Gravity) testing was performed using Viva Pro E analyzer; (2) The surveyor reviewed 2020 and 2021 calibration records with the laboratory supervisor, and identified calibration procedures had not been performed with calibration materials that included a low, mid, and high value as required every six months; (3) The surveyor reviewed calibration verification records for 2020 and 2021 for the analyzer and identified calibration verification had not been performed until 08/03 /2021 (due 07/2020 and 01/2021); (4) The surveyor then reviewed the records with the laboratory supervisor, who stated on 08/11/2021 at 11:25 am, calibration verification procedures had not been performed in 2020 as indicated above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's quality control specifications for 2 of 2 lot numbers. Findings include: (1) On 08/11/2021 at 11:00 am, the laboratory supervisor stated the following to the surveyor: (a) The laboratory performed urine drug testing on the Vivo Pro E analyzer,which included the following quantitative adulterant testing: (i) Oxidant (ii) Specific Gravity (iii) pH (b) Five levels of UTAK Adulterant Toxicology control materials were performed each day of patient testing; (2) The surveyor reviewed the manufacturer's instructions for the control materials which stated "Laboratories should establish their own statistical values for precision and expected ranges."; (3) The surveyor then reviewed QC (Quality Control) records for 2 lot number of control materials used from 10/12 /2020 through 08/11/2021 as follows: (a) Level 2 lot #C4786 - The laboratory had used the following ranges: (1) Oxidant range of 0.0 - 25.0 (2) pH range of 3.0 - 4.5 (b) Level 3 lot #C4565 - The laboratory had used the following range: (1) pH range of 8.0 - 10.5 (4) The surveyor asked the laboratory supervisor for the documentation to prove the laboratory had established their own mean and expected ranges. The laboratory supervisor stated on 08/11/2021 at 01:43 pm, the records could not be located.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the laboratory supervisor, the laboratory failed to provide normal reference intervals for 1 of 1 Urine Drug Screen test report. Findings include: (1) On 08/11/2021 at 11:00 am, the laboratory supervisor 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; (b) The laboratory performed quantitative Oxidant, Specific Gravity, and pH testing for urine specimens on the Viva Pro E analyzer. (2) The surveyor reviewed 1 test report for a patient tested on 08/11/2021 at 10:11 am. The report did not include a normal reference range for all of the analytes listed above; (3) The report was reviewed with the laboratory supervisor, who stated on 08/11/2021 at 11:28 am the patient report did not include a normal reference range as indicated above.