Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2172852	07/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pmo Medical, Pllc	401 E Broadway Court, Ste A, Sand Springs, 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 07/07/2021. The findings were reviewed with the laboratory director and laboratory supervisor during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. 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 an attestation statement was signed by the analyst for 1 of 3 events. Findings include: (1) On 07/07/2021, the surveyor reviewed 2020 and 2021 proficiency testing records, with the following identified: (a) First 2020 Chemistry Event - The attestation statement had not been signed by the analyst. (2) The surveyor reviewed the records with the laboratory supervisor. The laboratory supervisor stated on 07/07/2021 at 03:21 pm the attestation statement had not been signed by the analyst as indicated above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. 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 materials had been stored as required for 3 of 3 months. Findings include: (1) On 07/07/2021 at 10:45 am, the laboratory supervisor stated to the surveyor the laboratory performed urine drug testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, Oxycodone, pH, and Specific Gravity) on the Siemens Viva-Jr analyzer; (2) The surveyor reviewed temperature records from February 2020 through April 2020. The documented refrigerator temperatures were colder than 2 C (the coldest temperature allowed for the materials) during 3 of 3 months as follows: (a) February - 12 of 19 days temperatures had been documented (days 3,4,6,10,19,20,21,24,25,26,27,28); (b) March - 13 of 22 days temperatures had been documented (days 2,3,4,6,9,10,11,12,13,20,23,25,31); (c) April - 8 of 14 days temperatures had been documented (days 1,2,15,16,22,27,28,29). (3) The surveyor reviewed the records with the laboratory supervisor, who stated on 07/07/2021 at 3:40 pm, the refrigerator temperatures were unacceptable for the materials as indicated above.
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 Siemens Viva-Jr analyzer for 2 of 12 months. Findings include: (1) On 07/07/2021 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 Siemens Viva-Jr analyzer beginning 12/26/2019; (2) The surveyor reviewed 2020 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 for the analyzer and identified calibration verification had not been performed during the review period; (4) The surveyor then reviewed the records with the laboratory supervisor, who stated on 07/07/2021 at 03:24 pm, calibration verification procedures had not been performed in 2020 as indicated above.