

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2171947	(X3) Date Survey Completed 04/21/2021
Name of Provider or Supplier Pmo Medical, Pllc	Street Address, City, State 555 W Ruth, Sallisaw, 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 04/21/2021. The findings were reviewed with the laboratory director at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure an attestation statement was signed by the analyst for 1 of 2 events. Findings include: (1) On 04/21/2021, the surveyor reviewed 2020 proficiency testing records, with the following identified: (a) Second 2020 Chemistry Event - The attestation statement had not been signed by the analyst. (2) The surveyor reviewed the records with the laboratory director. The laboratory director stated on 04/21/2021 at 10:50 am the attestation statement had not been signed by the analyst as indicated above.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

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 director, the laboratory failed to ensure control materials were not used beyond the manufacturer's expiration date for 1 of 1 bottle of control material; and failed to ensure calibration materials were not used beyond the manufacturer's expiration date for 2 of 2 bottles. Findings include: (1) On 04/21/2021 at 09:35 am, the laboratory director 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) Three levels (level 3, 4, and 5) of UTAK quality control materials were performed each day of patient testing; (c) Two levels of Syva Specific Gravity calibrators were performed weekly. (2) On 04/21/2021 at 09:50 am, the surveyor observed the following: (a) One bottle of UTAK Validity Control Level 4 (Lot# C2685) with an expiration date of 03/31/2021; (b) One bottle of Syva Specific Gravity Validity Calibrator (Lot# 3T618UL-N1) with an expiration date of 03/26/2021; (c) One bottle of Syva Specific Gravity Validity Calibrator (Lot# 3T628UL-N1) with an expiration date of 03/26/2021. (3) The surveyor showed the expired material to the laboratory director. The laboratory director stated on 04/21/2021 at 10:00 am, the expired materials were available for use 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 director, 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 04/21/2021 at 09:35 am, the laboratory director stated to the surveyor an 11-panel urine drug screen (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiates, Oxycodone) testing was performed using Viva Pro E analyzer; (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 director, who stated on 04/21/2021 at 11:30 am, calibration verification procedures had not been performed in 2020 as indicated above.

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 director, the laboratory failed to provide normal reference intervals for 1 of 1 Urine Drug Screen test report. Findings include: (1) On 04/21/2021 at 09:35 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. (2) The surveyor reviewed 1 test report for a patient tested on 04/23/2020 at 11:33 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 director, who stated on 04/21/2021 at 11:55 am the patient report did not include a normal reference range as indicated above.