

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2171947	(X3) Date Survey Completed 08/13/2025
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 recertification survey was performed on 08/13/2025. 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.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director, QA (quality assurance) manager, and technical manager, the laboratory failed to retain temperature and humidity records, and maintenance logs for at least two years during the review period of January 2024 through the day of the survey. Findings include: (1) On 08/13/2025 at 09:30 am, the laboratory director stated 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; (2) Observation of the laboratory refrigerator identified patient urine specimens were stored in the refrigerator with a manufacturer's storage requirement of 2-8 degrees Centigrade (C); (3) A review of the operator's manual titled "Viva-ProE System Operator's Guide" under section A-7 "Technical Specifications" identified the manufacturer required the analyzer be operated at an ambient temperature of 15 to 32 degrees C (Centigrade), and a relative humidity of 15 to 85 % (non-condensing); (4) 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)</p>

Empty waste containers (ii) Fill treated water container (iii) Prime the system and check syringes (iv) Check cuvette blank (v) Check/replace 10% cleaning solution in the W position of sample rotor (vi) Check daily report (vii) Check reagent rotor compartment (viii) Check acid solution on reagent rotor (ix) Check reagent inventory (b) Weekly (i) Rinse probes (c) Monthly: (i) Clean treated water and waste containers (ii) Check/fill cooling fluid (iii) Clean instrument exterior (iv) Clean reagent rotor compartment (d) Quarterly: (i) Replace drying block (e) Semi-annual: (i) Replace stirrer belts (ii) Replace water filter (iii) Run the clean system procedure (f) Yearly: (i) Replace syringes (ii) Replace photometer lamp (g) Every 10,000 tests (i) Replace cuvette rotor (5) A review of temperature and humidity records and maintenance logs from January 2024 through the day of the survey identified temperature and humidity records, and maintenance logs could not be located for April 2024, and for the period between July 2024 to May 2025; (6) Therefore, since the temperature and humidity records and maintenance logs had not been maintained for at least 2 years, it could not be determined if the temperature and humidity had been monitored and were acceptable, and if the required maintenance had been performed for the periods stated above.

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 08/13/2025 at 09:30 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 8/13/2025 at 10:58 am confirmed Urine Drug Screen had not been verified for accuracy at least twice annually in 2023 and 2024 as indicated above.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the QA (quality assurance) manager

and technical manager, and a phone call with the laboratory director, the laboratory failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 08/13/2025, a review of personnel records for one person performing moderate complexity testing identified the following: (a) Testing Person - The initial training was completed on 10/11/2024. There was no evidence a semiannual evaluation had been performed to date. (2) Interview with the QA (quality assurance) manager and technical manager on 08/13/2025 at 09:15 am, and a phone call communication with the laboratory director following the survey on 08/19/2025 at 04:00 pm confirmed a semiannual competency evaluation had not been performed as stated above.