

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2174534	(X3) Date Survey Completed 07/02/2025
Name of Provider or Supplier Pmo Medical, Pllc	Street Address, City, State 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 recertification survey was performed on 07/02/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and technical manager at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory director, the laboratory failed to establish a written policy to assess the competency of the clinical consultant, based on the position responsibilities listed in Subpart M, for one of one person. Findings include: (1) On 07/02/2025, a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the clinical consultant based on the position responsibilities, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of September 2023 through the current date identified, although competencies, based on position responsibilities, had been performed for one of one person listed as the clinical consultant on 08/17/2023 and 08/22/2024, the assessment policy was not available for review; (3) The findings were reviewed with the laboratory director who stated on 07/02/2025 at 09:35 am, a written policy was not available, although competencies had been performed for the position as stated above.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

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 and QA (quality assurance) manager, the laboratory failed to verify the accuracy of Urine Drug Screen testing at least twice annually during the review period of September 2023 through the current date. Findings include: (1) On 07/02/2025 at 09:20 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 September 2023 through the current date identified the following: (a) No evidence the laboratory had participated in proficiency testing during the second 2024 event for all analytes; (b) No evidence the laboratory had participated in proficiency testing during the second 2023 event for the analyte Methadone. (3) Interview with the laboratory director on 07/02/2025 at 09:50 am confirmed Urine Drug Screen had not been verified for accuracy at least twice annually in 2023 and 2024 as indicated above.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) 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 and interview with the laboratory director and QA (quality assurance) manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Siemens Healthineers Viva-ProE analyzer during the review period of January 2025 through June 2025. Findings include: (1) On 07/02/2025 at 09:00 am, the laboratory director stated the laboratory performed urine drug testing (Amphetamines, Benzodiazepine, Buprenorphine, Cocaine, Methadone, and Oxycodone) using the Siemens Healthineers Viva-ProE analyzer; (2) 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) Check reagent rotor compartment (b) Monthly: (i) Clean treated water and waste containers (3) A review of maintenance records from January 2025 through June 2025 identified daily and monthly maintenance had not been documented as performed as follows: (a) Daily: (i) Between 01/01/2025 and 06/30/2025 (b) Monthly: (i) Between 01/01/2025 and 03/30/2025 (ii) Between 04/30/2025 and 06/02/2025 (4) Interview with the laboratory director and QA manager on 07/02/2025 at 10:30 am confirmed the maintenance procedures had not been documented as performed as stated above.