

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2174534	(X3) Date Survey Completed 08/24/2023
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 08/24/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and the Trinity consultant during an exit conference performed 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 follow their written policy to assess the competency of the clinical consultants, based on the position responsibilities as listed in Subpart M, for two of two persons. Findings include: (1) A review of the laboratory policy and procedure manual identified a policy titled, "Competency Check" which required the competency of the clinical consultant be assessed annually; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of December 2020 through the current date identified competencies, based on job responsibilities, had not been performed for two of two persons listed as clinical consultant on Form CMS-209 since 12/10/2020; (3) The findings were reviewed with the laboratory director who stated on 08/24/2023 at 11:00 am the policy had not been followed and competencies had not been performed for the clinical consultants since 12/10/2020.</p>
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, observation, and interview with the laboratory director, the laboratory failed to maintain lab temperatures were within the laboratory's acceptable range for three of three months reviewed. Findings include: (1) A review of temperature records identified the laboratory defined an acceptable laboratory temperature range of 20-30 degrees Celsius; (2) A review of the temperature records from July 2022, Jan 2023, and July 2023 identified: (a) July 2022 - two of 19 temperature readings were documented as less than 20 degrees Celsius; (b) January 2023 - One of 16 temperature readings were documented as less than 20 degrees Celsius; (c) July 2023 - One of 19 temperature readings were documented as less than 20 degrees Celsius; (3) The records were reviewed with the laboratory director who stated on 08/24/2023 at 11:00 am, the laboratory temperature had not been maintained as defined by the laboratory.

D6053

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

The technical consultant is responsible for 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 laboratory director, the technical consultant 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 performing testing between 10/20/2021 to 11/21/2022. Findings include: (1) A review of personnel records for one person performing moderate complexity testing since October 2021 identified the following for one of one person: (a) Testing Person #3 - The initial training was complete on 10/20/2021. There was no evidence an evaluation had been performed between 10/20/2021 and 11/21/2022. (2) The records were reviewed with the laboratory director who stated on 08/24/2023 at 11:00 am, a semiannual competency evaluation had not been performed.