Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2172852	06/07/2023
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 recertification survey was performed on 06/07/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the laboratory representative at the conclusion of the survey.
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, manufacturer's instructions, observation, and interview with the laboratory representative and testing person, the laboratory failed to ensure materials were stored as required by the manufacturer for one of four months reviewed; and failed to ensure the laboratory humidity was maintained as defined by the laboratory for four of four months reviewed. Findings include: REFRIGERATOR TEMPERATURES (1) On 06/07/2023 at 10:20 am, the laboratory representative stated Urine Drug Screen testing, which included the analytes Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiates, and Oxycodone using the Siemens Viva Jr analyzer; (2) On 06/07/2023 at 09:30 am, observation of the contents of the white Frigidaire refrigerator (a label on the refrigerator denoted it as "Refrigerator #1") identified the following: (a) One box of Siemens Syva Emit II Plus Oxycodone Assay, Lot #R4, manufacturer's storage requirement as stated on the box was 2-8 degrees C (Centigrade); (b) One box of Siemens Syva Emit II Plus Opiate Assay, Lot #R5, manufacturer's storage requirement as stated on the box was 2-8

	degrees C (Centigrade); (c) One box of Siemens Syva Emit II Plus Methadone Assay, lot #R5, manufacturer's storage requirement as stated on the box was 2-8 degrees C (Centigrade); (d) One box of Siemens Syva Emit II Plus Cocaine Metabolite Assay, Lot #S3, manufacturer's storage requirement as stated on the box was 2-8 degrees C (Centigrade). (3) A review of temperature records identified documented temperature records for refrigerator #1 and refrigerator #2, however it could not be determined if the records documented for refrigerator #1 were correct. Interview with the testing person on 06/07/2023 at 10:00 am confirmed Refrigerator #1 was denoted as Refrigerator #2 in the temperature records; (4) Review of the temperature records for Refrigerator #2 (these temperatures correlated to the refrigerator with the label that stated "Refrigerator #1") identified temperatures warmer than 8 degrees C for one of four months reviewed as follows: (a) January 2023 - Two of 15 temperature readings were documented as warmer than 8 degrees C. (5) The records were reviewed with the laboratory representative and testing person. Both stated on 06/07/2023 at 11:00 am, the materials had not been stored stored as required by the manufacturer. HUMIDITY (1) A review of the operator's manual for the Siemens Viva Jr analyzer on page A-7 under "Environment Specifications" identified the manufacturer required the analyzer be operated at a humidity of 15-85%; (2) A review of humidity records identified the laboratory defined an acceptable laboratory humidity range of 20-70%; (3) A review of the humidity records from January through April 2023 identified the humidity readings were less than 20% (the lowest limit as defined by the laboratory) for four of four months as follows: (a) January 2023 - Ten of 14 humidity readings were documented as less than 20%; (b) February 2023 - Six of 16 humidity readings were documented as less than 20%; (c) March 2023 - Seven of 18 humidity readings were documented as less than 20%; (d) April 2023 - One of 14 humidity readings were documented as less than 20%. (4) The records were reviewed with the laboratory representative who stated on 06/07/2023 at 11:00 am, the laboratory humidity had not been maintained as defined by the laboratory.