Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1093966	09/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pm Healthcare, Llc	701 Leighton Avenue, Anniston, AL	

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
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 the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC) and Testing Personnel 2 (TP2), the laboratory failed to verify the accuracy for the Urine Drug Screen (UDS) analytes, Benzodiazepines, Cocaine Metabolites, Methadone, Opiates and Phencyclidine, all non-regulated analytes. The surveyor noted five of the eleven UDS analytes had unsuccessful PT performance evaluation for the 2023 Chemistry Miscellaneous-2nd Event. The findings include: 1. A review of the API PT records revealed the laboratory had unsatisfactory scores on the 2023 Chemistry Miscellaneous-2nd Event for the following UDS analytes. A) Benzodiazepines 33% B) Cocaine Metabolites 33% C) Methadone 33% D) Opiates 33% E) Phencyclidine 33% 2. The TC and TP2 confirmed the above findings during the exit conference on 09-17-2025 at 1:37 PM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) 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 direct observation during the laboratory tour, a review of electronic testing

	history logs and an interview with the Technical Consultant (TC) and Testing Personnel 2 (TP2), the laboratory failed to ensure in-date Quality Control (QC) material was utilized for urine Creatinine before patient testing on one of the 30 days in September 2025. The findings include: 1. Direct observation of the refrigerated reagents, calibrators and QC materials during the laboratory tour revealed the Creatinine-Detect QC 1.3 mg/dL, Lot 75247100 had expired on 08-31-2025. The laboratory used it prior to patient testing on 09-02-2025. 2. TP2 stated the review of the electronic testing history logs revealed 84 patients were performed on 09-02-2025 with the expired QC. 3. During the exit conference on 09-17-2025 at 1:37 PM, the TC and TP2 confirmed the above findings.
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 reviews of the Microgenics MGC 240 analyzer maintenance records, the analyzer's maintenance checklist, and an interview with the Technical Consultant (TC) and Testing Personnel 2 (TP2), the laboratory failed to document daily maintenance on two of the 31 days in August 2024. The findings include: 1. A review of the Microgenics MGC 240 analyzer maintenance records revealed the laboratory failed to document the daily maintenance on 08-12-2024 and 08-27-2024 when patient testing was performed. 2. A review of the analyzer's maintenance checklist revealed procedures to perform beginning and end of day, as follows: Beginning of Day: a) Check and/or Fill DI Water Reservoir. b) Check and/or Fill 2% Alkaline Water Reservoir. c) Check and/or Fill 1% Acid Water Reservoir. d) Empty Waste Reservoir. e) Check and Replace Printer Paper. f) Check Reagent Compartment Temperature (by touch). End of Day: a) Wipe Probes with DI Water 3. The TC and TP2 confirmed the above findings during the exit conference on 09-17-2025 at 1:37 PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 reviews of the Microgenics MGC 240 analyzer Calibration records,and an interview with the Technical Consultant (TC) and Testing Personnel 2 (TP2), the laboratory failed to perform and document C-V procedures at least once every six months per CLIA regulation. The surveyor noted no documentation for five out of five possible C-V from the date of the last survey, 06-20-2023 to the date of the current survey, 09-17-2025. The findings include: 1. A review of the calibration records for the Microgenics MGC 240 analyzer revealed the Urine Drug Abuse (DOA) analytes were calibrated with less than three calibrators and performed with two levels of Quality Control (QC) each day of patient testing, however there was no evidence of C-V documentation in 2023-2025. 2. A further review of the calibration and Quality Control (QC) records for the Microgenics MGC 240 analyzer revealed each DOA analyte was calibrated with less than three calibrators and two levels of QC materials each day of patient testing. 3. During the exit conference on 09-17-2025 at 1: 37 PM, the TC and TP2 confirmed the above findings.