Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2059757	11/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Pain And Weight Loss	131 Welton Way, Suite A, Mooresville, NC	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon review of 2022 and 2023 CAP-PT (proficiency testing) records and review of the laboratory's policies and procedures, TP (Testing Personnel) who participated in PT events failed to sign Attestation Forms for 3 of 4 CAP-PT events. Findings: Review of the 2022 and 2023 CAP-PT records revealed that TP who performed the peak review of LC/MS (liquid chromatography/mass spectrometry) data for the following events did not sign Attestation Forms for these DMPM (Drug Monitoring and Pain Management) events: 1. 2023 DMPM Event A 2. 2022 DMPM Event B 3. 2022 DMPM Event A Review of the laboratory's "System Level Procedure: Proficiency Testing" policy revealed the following in "5. Procedures: 5.3.10 - Document each round of Proficiency Testing. These records will include..... Attestation Form-signed by the Laboratory Director and the participating testing personnel."
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 upon review of 2022 and 2023 calibration verification records and interview with the LD (Laboratory Director) on 11/16/23, the laboratory failed to perform calibration verification activities that included a maximum value near the upper limit of the laboratory's reportable range for 1 of 1 analyte quantified on its Thermo Fisher Indiko chemistry instrument. Findings: Review of the October 2023 calibration verification records for urine alcohol performed on the Thermo Fisher Indiko instrument revealed the following data: Three concentrations of linearity material were used to assess the reportable range of urine alcohol. These three samples demonstrated the following concentrations: 18.7 ng/mL, 73.5 ng/mL, 141.7 ng/mL Review of the May 2022 calibration verification records for urine alcohol performed on the Thermo Fisher Indiko instrument revealed the following data: Three concentrations of linearity material were used to assess the reportable range of urine alcohol. These three samples demonstrated the following concentrations: 24.7 ng/mL, 98.6 ng/mL, 192.3 ng/mL In interview at approximately 1:25 p.m., the LD stated that the laboratory quantitatively reports urine alcohol values within a range of 50-300 ng /mL. The LD reviewed the findings and stated that numerous vials are contained within the kit used to perform calibration verification activities for urine alcohol and that Testing Personnel was not using the correct vials with the appropriate concentrations.