Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2059757	04/19/2022
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 on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 PT(proficiency testing) records, and absence of documentation 4/19/22, the laboratory director and testing personnel failed to attest that the alternate performance PT was tested in the same manner as patient specimens for 8 of 8 events in 2020 and 2021. Findings: The laboratory's "Proficiency Testing" procedure states, "5.4 Alternate Performance Assessment. 5.4.1...For those analytes/tests where commercially available CAP or non-CAP proficiency testing material are not options, perform alternative performance assessment twice per calendar year... 5.4.10 Document each round of alternative performance assessment testing. These records will include: Copy of the attestation form signed by the Laboratory Director and the participating testing personnel...." Review of 2020, 2021, and 2022 PT records revealed the laboratory director and testing personnel had not signed attestation statements for the following alternate performance PT events: 1. 2020 ETOH- ALT PT- I and II events; 2. 2020 ALT PT-I and II events; 3. 2021 ETOH- ALT PT- I and II events; 4. 2021 ALT PT-I and II events.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test

	system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of performance verification records and interview with laboratory director (LD) 4/19/22, the laboratory failed to include operator variance in the precision verification of the Bio-Lis analyzer, failed to perform a performance verification of the laboratory information system (LIS) for the Bio-Lis analyzer and failed to verify specimen stability for the testing performed on the Bio-Lis analyzer. 1. The laboratory failed to include operator variance in the precision verification of the Bio-Lis analyzer. Findings: Review of performance verification records revealed the raw data documenting variance included day-to-day, run-to-run, and within run variance for precision verification. The records failed to include operator variance. Interview with LD at approximately 11:00 a.m. confirmed the records failed to include operator variance. She stated the precision verification of the Bio-Lis analyzer was performed by one service representative. 2. The laboratory failed to perform a performance verification of the LIS for the Bio-Lis analyzer. Findings: Review of performance verification records revealed no documentation of a performance verification of the LIS for the Bio-Lis analyzer. Interview with LD at approximately 11:00 a.m. confirmed the records did not include a performance verification of the LIS for the Bio-Lis analyzer. She stated she knew it was performed but she could not locate the records needed to document it. 3. The laboratory failed to verify specimen stability for the testing performed on the Bio-Lis analyzer. Findings: Review of performance verification records revealed no documentation of a specimen stability verification for the testing performed on the Bio-Lis analyzer. Interview with LD at approximately 11:00 a.m. confirmed the laboratory failed to perform a verification of specimen stability. She stated she was unaware they would need to verify specimen stability and she thought they could use the specimen stabilities stated in the manufacturer's package inserts.