Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0693402	05/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cornerstone Medical Group	914 Vista Drive, Dalton, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 13, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) evaluation reports and an interview with testing personnel (TP), the laboratory failed to document corrective actions for unacceptable results received on the 2024 event #2 and 2025 event #1. Findings: 1. Review of the API PT 2024 event #2 revealed sample CH10 had an unacceptable result for Total Protein (TP). Score 80%- No corrective action was documented for the missed PT sample. 2. Review of the API PT 2025 event #1 revealed sample GLY-05 had an unacceptable result for Glycated Hemoglobin (GLY). Score 80%- No corrective action was documented for the missed PT sample. 3. Interview with the TP #1 (CMS 209 form) in the office area outside the laboratory at 12:10 pm on 5/13/25 confirmed the findings above.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required

	prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the laboratory testing rocesses Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing, including, lab director, clinical consultant, technical consultant, and testing personnel. 2. An interview with staff #2 (CMS 209) in the laboratory on 5/14/25 at 11: 25 a.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure for the aforementioned staff.