Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0257012	07/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Woodall, Wilson & Manley Md Llp	101 Houston St, Barnesville, 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 July 14, 2026. 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:
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on lab report review and staff interview, the laboratory failed to include the reference range information on the in-house laboratory hematology test reports. Findings: 1. A review of patient test report #08061957 revealed the report did not contain reference range values for the analytes tested. 2. Interview with staff #1 (CMS 209) in the breakroom on 7/14/26 at 12:10 PM confirmed the finding above.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or

	she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview, the laboratory director (LD) failed to delegate training and competency duties to a qualified employee. Findings include: 1. A review of personnel training records revealed 4 of 5 testing personnel (TP) (CMS 209) were trained by an unqualified employee (TP#2 CMS 209). 1 of 5 TP was trained by an unqualified employee who is no longer employed by the laboratory. 2. Review of competency evaluations revealed 4 of 5 testing personnel (TP) (CMS 209) were evaluated by an unqualified employee (TP#2 CMS 209). 1 of 5 TP was evaluated by an unqualified employee who is no longer employed by the laboratory. 3. Interview with staff #1 (CMS 209 form) on 7/14/26 at 12:08 PM in the breakroom, confirmed the findings above.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results were found to be unacceptable or unsatisfactory. Findings: 1. Review of proficiency testing records revealed there was no documented corrective action for 2026 Event 1 White Blood Cell (WBC) Differential with a score of 80%. 2. Interview with staff #1 (CMS 209) in the breakroom on July 14, 2026, at 12:00 p.m. confirmed the finding 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 performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each required position for a moderate complexity lab. The LD failed to have duties and responsibilities written for the Technical consultant (TC), Clinical Consultant (CC), or the Lab Director (LD). 2. An interview with Staff #1 (CMS 209) in the breakroom on 7/14/26 at 12:00 p.m. confirmed the SOP did not contain a duties and responsibilities for the positions listed above.