Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235758	(X3) Date Survey Completed 10/21/2025
Name of Provider or Supplier Wood Health Care Clinic P C	**Street Address, City, State** 1307 Lafayette Avenue, Moundsville, WV	

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 routine recertification survey was conducted at Wood Health Care Clinic P C on October 21, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the CDS Medonic M16 analyzer verification records, hematology policies and procedures, Medonic M16 test reports, and interview with testing

	personnel (TP1), the laboratory failed to (b)(10) include the correct reference intervals (RI) for 3 of 11 parameters reported in a complete blood count with differential (CBC /DIFF) in the policies and procedures. Findings: 1. Review of the CDS Medonic M16 analyzer verification records revealed the appropriateness of the reference intervals (RIs) for the laboratory population was verified for 11 of 11 parameters in the CBC /DIFF when the analyzer was put into use (4/11/2024). 2. Review of hematology policies and procedures identified stated RIs in the "Medonic-M-Series" policy for all 11 parameters tested in a CBC/DIFF. 3. The RIs for the GRAN%, MID%, and LYMPH% parameters in the analyzer verification records did not match those stated in the written policy. 4. Review of a patient CBC/DIFF final report from the CDS Medonic M16 hematology analyzer (specimen 5188 from 10/21/2025) revealed that the RIs listed in the Medonic M16 analyzer verification records for the 3 parameters were the values being reported. 5. During an interview, 10/21/25 at 9:55 AM, TP1 stated the RIs for the 3 parameters had not been updated in the written policy to match the verification data when the new instrument was put into use in April of 2024.