

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2153215	(X3) Date Survey Completed 10/16/2024
Name of Provider or Supplier Wvu Medicine - Weston	Street Address, City, State 107 Staunton Dr, Weston, 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 WVU Medicine- Weston on October 16, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of an EPIC final hematology test report, lack of documentation, and interview, the laboratory failed to provide the reference intervals for 3 of 17 parameters tested in a complete blood cell count (CBC) with automated differential, performed with the Sysmex XP-300 hematology analyzer. Findings: 1. Review of a test patient's final report (10/16/24) for a CBC with automated differential from EPIC revealed test results for 17 parameters. No stated reference intervals for 3 parameters in the automated differential (neutrophil %, monocyte %, and lymphocyte %) were listed on the final report. 2. An interview with the testing personnel (TP1), 10/16/24 at 9:40 AM, confirmed that no listed reference intervals for the neutrophil %, monocyte %, and lymphocyte % could be located on the final test report for a CBC with automated differential. 3. An exit interview with the technical supervisor, 10/16/24 at 10:30 AM, confirmed the lack of reference intervals for 3 of 17 CBC parameters on the final test report.</p>