

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236838	(X3) Date Survey Completed 02/24/2026
Name of Provider or Supplier Manchin Clinic	Street Address, City, State 100 Main Street, Farmington, 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 Manchin Clinic on February 24, 2026, 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 deficient practices are cited and explained below.
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology policies and procedures, DxH 520 analyzer verification records, DxH 520 instructions for use (IFU), lack of documentation, and interview with testing personnel (TP1), the laboratory director (LD) failed to ensure that updated policies and procedures for the operation of DxH 520 hematology analyzer for complete blood count (CBC) testing were available to testing personnel from the first date of the new analyzer use (March 15, 2024) thru date of survey. Findings: 1. Review of hematology procedures identified a procedure for CBC testing on the AcTDiff2 analyzer, "ACT DIFF 2 CBC Analysis Quick Guide & Flag Criteria", signed and dated as reviewed by the LD on 6/4/24 and 7/4/25. 2. Review of the verification records for the hematology DxH 520 analyzer revealed a go live date for patient CBC testing of 3/15/2024. 3. Review of the IFU for the DxH 520 analyzer revealed no LD signature and date. TP1 could not locate any other policies or procedures for operation of the DxH 520 analyzer. 4. During an interview, 2/24/26 at 11:20 AM, TP1 stated the written polices and procedures had not been updated from the old AcTDiff 2 with the new DxH 520 analyzer. 5. An exit interview with TP1, 2/24 /26 at 1:00 PM, confirmed the LD had not approved new written policies or procedures for CBC testing on the DxH 520 from March 2024 thru date of survey.</p>