Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0916810	09/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hardy County Medical Services	8 Lee Street, Moorefield, 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 Hardy County Medical Services on September 10, 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, proficiency testing (PT) records, lack of documentation, and interview with testing personnel (TP1), the laboratory failed to complete any accuracy verifications in 2025 for Histopathology. Findings: 1. Review of "Proficiency Testing" procedure identified "semi-annually, the tech or manager will randomly select and send two cases containing the original slides, label it with only the surgical number, and send it over for a microscopic examination by a Board Certified Dermatopathologist" as an in-house program for verification of accuracy in Histopathology. 2. Review of 2025 PT records (January thru date of survey) revealed slides for an in-house accuracy evaluation were sent to Rabkin for review on 8/4/2025. No documentation the accuracy evaluation for Histopathology was completed could be located. 3. During an interview with TP1, 9/10/2025 at 9:20 AM, TP1 agreed that no accuracy verification for Histopathology had been completed for 2025.
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 a tour of the laboratory, review of written policies and procedures, and interview with testing personnel (TP1) the laboratory failed to update the (b)(3) step by step procedure for the Hematoxylin and Eosin (H&E) staining process on the Takura Tissue-Tek automatic slide stainer. Findings: 1. A tour of the laboratory, 9/10 /25 at approximately 10:00 AM, identified 1 staining process (H&E) used by the laboratory. 2. A review of MoHs policies and procedures for staining (Hematoxylin and Eosin Stain) revealed set times for each step in the staining method. 3. During an interview with testing personnel (TP1), 9/10/25 at approximately 10:05 AM, the settings for the H&E staining program were reviewed on the Takura Tissue-Tek automatic slide stainer. Two of the fifteen times set in the H&E staining program for each step did not match the times defined in the written policy. TP1 stated the written procedure for the MoHs staining process had not been updated with the timed settings currently in use by the laboratory.