Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 51D1082418	**(X3) Date Survey Completed** 05/20/2026
Name of Provider or Supplier Manchin Clinic South Llc	**Street Address, City, State** 181 Middletown Loop, Whitehall, 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 South LLC on May 20, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with CLIA regulations 42 CFR 493, Requirements for Laboratories. Specific noncompliance found and deficiencies cited are explained below.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of currently in-use refrigerated DxH 500 quality control (QC) materials, review of DxH 500 Series Control instructions for use (IFU), lack of labeling, interview with the testing personnel (TP1) and interview with the technical consultant (TC), the laboratory failed to (3) label the date opened and expiration dates on three of three vials of QC material, in accordance with the manufacturer instructions for use. Findings: 1. During a tour of the laboratory, 5/20/26 at 11:20 AM, the state surveyor observed the QC materials in the refrigerator, including three opened vials of DxH 500 Series Control (Tri Level 352618411 Abnormal Low, 362618412 Normal, 372618413 Abnormal High) in a cup labeled currently in use. There were no written open or expiration dates on 3 of the 3 vials of QC. 2. During an interview, 5/20/26 at 11:21 AM, TP1 confirmed the three unlabeled vials of QC materials were the current materials ran for external daily QC on the DxH 500 analyzer. 3. Review of the instructions for use for the"Table of Expected Results" for the Tri Level DxH 500 Series Control (lot 352618411, 362618412, 372618413)

	identified an expiration date of 16 days from date opened. 4. During an interview, 5/20 /26 at 12:00 PM, the TC verified the three QC vials had no labeled open and expiration dates.
D5813	TEST REPORT CFR(s): 493.1291(g) (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of hematology policies and procedures, May 2026 complete blood count (CBC) test reports from the Beckman Coulter DxH 500 analyzer, electronic medical record (EHR) in the Orchard laboratory information system (LIS), lack of documentation, an interview with the technical consultant (TC), and exit interview with the laboratory director (LD), the laboratory failed to document the notification to the ordering provider for two of two panic value results (patient 1 and patient 2) for hemoglobin released in May 2026. Findings: 1. Review of the "Critical Values" policy revealed the stated panic value (critical result) for hemoglobin as "values less than 7.0 g/dl and greater than 18.0 g/dl." 2. Review of 68 CBC hematology results (May 1 2026 thru date of survey) from DxH 500 analyzer revealed two critical hemoglobin results released and no documentation of the notification to the ordering provider: 5/4 /26 Patient 1 (26124014) hemoglobin 6.47 g/dL 5/11/26 Patient 2 ID (26131004) hemoglobin 18.65 g/dL 3. Review of the documentation in the Orchard EHR for the two patients confirmed the lack of provider notification documentation for the critical hemoglobin values of 6.47 g/dL (Patient 1) and 18.65 g/dL (Patient 2) . 4. During an interview on 5/20/26 at 12:00 PM, the TC verified the critical values for the two patients had no notifications to the ordering provider documented on the retained analyzer copy or in the EHR. 5. An exit interview with the LD, 5/20/26 at 1:00 PM, confirmed the findings.