Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0910926	12/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Minnie Hamilton Health Care Center Inc	186 Hospital Hill, Grantsville, 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 completed for Minnie Hamilton Health Care Center Inc. on December 17, 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.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) (d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the verification records for the BCID2 PCR test panel on the Biofire Torch analyzer, BCID2 PCR test panel manufacturer instructions for use (IFU), BCID2 patient test results from the Biofire Torch analyzer, external quality control (QC) records, and interview with the general supervisor (GS), the laboratory failed to perform two levels of QC for the BCID2 PCR test panel on 10 of 12 days of patient testing from June 18, 2025 thru date of survey. Findings: 1. Review of the 2025 Biofire Torch BCID2 verification records revealed the laboratory director reviewed and approved the performance specifications for the BCID2 PCR test panel on the analyzer on 4/17/2025. 2. Review of the manufacturer IFU for the BCID2 test panel on the Biofire Torch analyzer revealed no specific frequency for the performance of external quality control (QC) for the moderate complex BCID2 PCR test panel. 3. Review of QC records (June 2025 thru November 2025) identified two

	levels of external QC performed on two days of patient testing (6/18 and 7/2). 4. Review of 16 BCID2 PCR test panel patient results (June 2025 thru November 2025) identified 13 results released on 10 testing days with no performance of two levels of external QC: 6/21: patient 25034088, patient 25034087 6/23: patient 25034351 7/11: patient 25037918 7/15: patient 25038687, patient 25038359 7/19: patient 25039587 9 /29: patient 25051371 9/30: patient 25051526 11/12: patient 25058800, patient 25058828 11/18: patient 25059850 11/21: patient 63447 5. The GS could not locate an Individualized Quality Control Plan (IQCP) for the performance of external QC for the BCID2 PCR test panel less often than each day of patient testing. 6. An interview with the GS, 12/17/25 at 8:30AM, verified the lack of performance of two levels of external QC materials each day of patient testing for 10 of 12 days in time period reviewed for the BCID2 PCR test panel.