Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 51D2108787	**(X3) Date Survey Completed** 06/19/2024
Name of Provider or Supplier Manchin Clinic Of Bridgeport	**Street Address, City, State** 409 West Main Street, Bridgeport, 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	An initial certification survey was performed at Bridgeport Manchin Clinic on June 19, 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.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures (P&P), calibration records, lack of documentation, and an interview with the technical consultant (TC), the laboratory failed to perform and document calibration of the ACT2 Diff analyzer at the frequency determined by the laboratory in 2023. Findings: 1. A review of hematology P&P identified the frequency of calibration for the ACT2 Diff as every 6 months, as a step in the process of resolving QC issues, and after major maintenance. 2. A review of ACT2 Diff calibration records (2022 and 2023) identified a documented calibration performed on 10/27/2022. No documentation of calibration performed between 10/28/2022 and the analyzer being taken out of service in January

	of 2024 could be located. 3. An interview with the TC, 6/19/24 at 9:00 AM, confirmed the lack of the required calibrations for the ACT2 Diff hematology analyzer from 10/28/2022 thru January 2024.