Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2108787	01/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Manchin Clinic Of Bridgeport	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 off site, proficiency testing (PT) desk review was conducted for Bridgeport Manchin Clinic on January 7, 2025, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. The identified unsuccessful participation is an initial occurrence and explained below.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and interview with testing

	personnel (TP1), the laboratory failed to successfully participate in PT for the specialty 0760 Hematology in two consecutive testing events of 2024. Refer to D2123.
D2123	HEMATOLOGY CFR(s): 493.851(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and interview with testing personnel (TP1), the laboratory failed to successfully participate in PT for 6 of 6 CMS regulated analytes in two consecutive testing events for 2024 resulting in unsuccessful participation for the specialty 0760 Hematology. Findings: 1. Review of CASPER 155D PT report revealed the following unsatisfactory scores in the specialty 0760 Hematology: Event 2 2024: 0765 WBC DIFF 0%, 0775 RBC 0%, 0785 HCT 0%, 0795 HGB 0%, 0805 WBC COUNT 0%, 0815 PLATELETS 0% Event 3 2024: 0765 WBC DIFF 0%, 0775 RBC 0%, 0785 HCT 0%, 0795 HGB 0%, 0805 WBC COUNT 0%, 0815 PLATELETS 0% 2. Review of API PT evaluations for 2024 confirmed the unsatisfactory performance of 6 of 6 regulated analytes and identified the unsatisfactory performance as "failure to participate" in Event 2 and Event 3 of 2024. 3. During a phone interview with TP1, 1/8/25 at 8:50 AM, TP1 stated the laboratory had performed the testing for the hematology PT events but had not been able to submit them to API.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and interview with testing personnel (TP1), the laboratory director (LD) failed to ensure the laboratory successfully participated in a PT program for the specialty 0760 Hematology in two consecutive testing events of 2024. Refer to D2123.