Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 51D0236838	**(X3) Date Survey Completed** 10/06/2025
Name of Provider or Supplier Manchin Clinic	**Street Address, City, State** 100 Main Street, Farmington, 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 offsite proficiency testing (PT) desk review was conducted for Manchin Clinic on October 6, 2025, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. The identified unsuccessful participation in PT 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 and laboratory PT evaluations from the American Proficiency Institute (API), the laboratory failed to perform successfully in two consecutive testing events in 2025 for the analyte #0785

	hematocrit, resulting in an initial occurrence of unsuccessful participation. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report and laboratory PT evaluations from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the analyte #0785 hematocrit in two consecutive testing events in 2025, resulting in an initial occurrence of unsuccessful participation in PT. Findings: 1. Review of CASPER 155D PT report revealed the following unsatisfactory scores for for analyte #0785 hematocrit: 60% 2025 event 1 0% 2025 event 2 2. Review of 2025 API Hematology PT evaluation reports for testing events 1 and 2, confirmed the unsatisfactory scores and unsuccessful performance for analyte #0785 hematocrit in two consecutive testing events and the resulting occurrence of unsuccessful participation.