

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236838	(X3) Date Survey Completed 07/24/2025
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 July 24, 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 is an initial occurrence and explained below.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report and PT evaluations from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for chemistry analytes #0305 total bilirubin in two of three</p>

consecutive events and #0355 chloride and #0475 sodium in two consecutive testing events, resulting in an initial occurrence of unsuccessful participation in PT. Refer to D2096.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the analyte #0305 total bilirubin in two of three consecutive PT events in 2024 and 2025, and analytes #0355 chloride #0475 sodium in two consecutive 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 analyte #0305 total bilirubin: 40% 2024 event 3 0% 2025 event 2 2. Review of CASPER 155D PT report revealed the following unsatisfactory scores for analyte #0355 chloride: 0% 2025 event 1 0% 2025 event 2 3. Review of CASPER 155D PT report revealed the following unsatisfactory scores for analyte #0475 sodium: 0% 2025 event 1 0% 2025 event 2 4. Review of 2024 and 2025 API Chemistry Core PT evaluation reports confirmed the unsatisfactory scores for analyte #0305 total bilirubin in two of three consecutive PT events and analytes #0355 chloride and #0475 sodium in two consecutive PT events.