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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 51D0236838 | (X3) Date Survey Completed 06/04/2026 |
| 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 |
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| D0000 | An offsite proficiency testing (PT) desk review was conducted for Manchin Clinic on June 4, 2026, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with 42 CFR 493, Requirements for Laboratories. The identified unsuccessful participation is an initial occurrence with the following condition level deficiencies found to be out of compliance: D2016- 42 CFR 493.803 Condition: Successful Participation [proficiency testing] |
| 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 a desk review of proficiency testing (PT) records from the Certification and</p> |

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| | <p>Survey Provider Enhanced Reporting (CASPER) 0155 report and American Proficiency Institute (API) 2025 and 2026 records, the laboratory failed to successfully participate in a proficiency program approved by Health & Human Services (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to return PT results within the required timeframe, resulting in unsuccessful participation for the hematology specialty (#0760) in two of three consecutive testing events (2025-3 and 2026-1) and analyte white blood cell (#0805) in two consecutive testing events (2025-3 and 2026-1). Refer to D2127, D2130, and D2131.</p> |
| <p>D2127</p> | <p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 155D Report and API 2026 records (1st Event), the laboratory failed to return proficiency testing results within the required timeframe in the specialty of hematology for one of one testing events in 2026. Findings: 1. A review of CASPER 155D Report revealed the following results: Hematology 2026- 1st Event the laboratory received an unsatisfactory score of 0% for the specialty of hematology (#0760) and 0% for the analytes WBC DIFF (#0770), RBC (#0775), HCT (#0785), HGB (#0795), WBC Count (#0805), platelets (#0815). 2. A review of API 2026 1st event records confirmed the above score of 0% and noted "failure to participate" on the performance evaluation for the API 2026 1st testing event, resulting in an unsuccessful participation for the specialty of hematology (#0760) and the white blood cell analyte (#0805).</p> |
| <p>D2130</p> | <p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the CASPER 0155D Report, API 2025 records (3rd Event), API 2026 records (1st Event), the laboratory failed to achieve satisfactory performance (at least 80%) for the analyte white blood cell (#0805) for two consecutive proficiency testing events in the specialty of hematology, resulting in an initial occurrence of unsuccessful performance for the analyte. Findings: 1. Review of the CASPER 155D Report revealed the following results: Hematology 2025- 3rd Event the laboratory received an unsatisfactory score of 60% for analyte white blood cell (#0805) Hematology 2026- 1st Event the laboratory received an unsatisfactory score of 0% for analyte white blood cell (#0805) 2. A review of the API 2025 and 2026 records for the laboratory confirmed the results.</p> |
| <p>D2131</p> | <p>HEMATOLOGY CFR(s): 493.851(g)</p> |

(g) Failure to achieve an overall testing event score of satisfactory performance for 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 a proficiency testing (PT) desk review of the CASPER 155D report, API 2025 (2nd event), and API 2026 records (1st event), the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two out of three consecutive testing events in the specialty of hematology (#0760), resulting in an initial occurrence of unsuccessful performance for the specialty. Findings: 1. A review of the CASPER 155D report revealed the following: Hematology 2025- 2nd Event The laboratory received an overall unsatisfactory score of 76% for the specialty of hematology (#0760) Hematology 2026- 1st Event The laboratory received an overall unsatisfactory score of 0% for the specialty of hematology (#0760). 2. A review of records for PT from API for 2025 and 2026 confirmed the findings.