| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 24D1003005 | 12/08/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Native American Community Clinic | 1213 E Franklin Ave, Minneapolis, MN | |

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** | The following deficiencies are a result of a December 9, 2025 desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company's evaluations. The Native American Community Clinic laboratory was found to be out of compliance with the Conditions of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493). The following condition-level deficiency was cited: D2016 - 42 C.F.R. 493.803 Condition: Successful participation (proficiency testing) . |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>. Based on a desk review of proficiency testing records from the Center for Medicare |

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| | and Medicaid Services (CMS) Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Hematology for the analyte Hematocrit. Refer to D2130. . |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on review of proficiency testing (PT) reports from CMS and WSLH, the laboratory failed to achieve successful PT performance (80% or better) for Hematocrit (HCT) testing under the specialty of Hematology in two of three consecutive PT events in 2025. Findings include: 1. Review of the CMS CASPER 0155D report revealed the following results: Hematology 2025 2nd Event: The laboratory received an unsatisfactory score of 40% for HCT. Hematology 2025 3rd Event: The laboratory received an unsatisfactory score of 40% for HCT. 2. Review of WSLH 2025 PT records (WSLH PT 2025-HemeReg2 and WSLH PT 2025-HemeReg3 Proficiency Testing Evaluations) confirmed the laboratory received the above results. . |