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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 24D0864231 | (X3) Date Survey Completed 04/13/2026 |
| Name of Provider or Supplier Shakopee Dakota Clinic | Street Address, City, State 2330 Sioux Trail Nw, Prior Lake, 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 |
|---------------------------|---|
| D0000 | The Shakopee Dakota Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the proficiency testing desk review survey performed on April 13, 2026. The following condition-level deficiencies were cited: 493.803 Successful Participation The following standard-level deficiencies were cited: 493.841 Routine chemistry . |
| 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 Survey Provider Enhanced Reporting (CASPER) 0155 report and API (American</p> |

Proficiency Institute) records from 2025 and 2026, 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 subspecialty of Routine Chemistry for the analyte Sodium. 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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and American Proficiency Institute (API) records, the laboratory failed to successfully participate in proficiency testing (PT) for the analyte Sodium under the subspecialty Routine Chemistry in two out of three consecutive testing events in 2025 and 2026, constituting unsuccessful performance. Findings include: 1. The CASPER Report 0155D and the API 2026 Chemistry - Core 1st Event and API 2025 Chemistry - Core 3rd Event Performance Summary and Comparative Evaluations were reviewed on April 13, 2026. 2. The laboratory received unsatisfactory performance for Sodium in two out of three consecutive events in 2025 and 2026, leading to unsuccessful participation as indicated in the above reports. See below. Unsatisfactory Sodium PT events -Score of 20% during the 3rd event of 2025 -Score of 20% during the 1st event of 2026 .