

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0409330	(X3) Date Survey Completed 10/19/2023
Name of Provider or Supplier Trenton Community Clinic	Street Address, City, State 331 4th Ave E, Trenton, ND	
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
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 American Proficiency Institute proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte total bilirubin for two of three consecutive events in 2023 (Event 1 and Event 3), resulting in unsuccessful performance. (Refer to D2096)
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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 proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte total bilirubin in two of three consecutive events in 2023 (Event 1 and Event 3), resulting in unsuccessful performance. Findings include: 1. Review of 2023 American Proficiency Institute (API) proficiency testing reports on 10/19/23 for the analyte total bilirubin revealed the following results: Event 1-2023 - 60% Sample Lab Results Acceptable Range #01 0.7 0.2 - 1.1 #02 0.1 0.0 - 0.5 #03 5.4 3.2 - 5.0 #04 1.3 0.6 - 1.5 #05 3.7 2.2 - 3.4 Event 3-2023 - 20% Sample Lab Results Acceptable Range #11 2.9 3.3 - 5.1 #12 0.7 0.5 - 1.4 #13 2.5 2.7 - 4.1 #14 2.0 2.1 - 3.3 Sample Lab Results Acceptable Range #15 1.5 1.7 - 2.7 The specialty of chemistry requires a score of 80% or greater for satisfactory performance. 2. During a telephone interview at 10:45 a.m. on 10/19/23, the laboratory supervisor (#1) confirmed the laboratory had scored 60% in Event 1 and 20% in Event 3 in 2023 for total bilirubin.