

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408659	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Towner County Medical Center	Street Address, City, State 228 1st Ave, Cando, 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
D0000	A proficiency testing desk review conducted on August 19, 2024 found the laboratory out of compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 493.1780. The following condition level deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful Participation D6076 - 42 CFR 193.1441 Condition: Laboratory Director
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 Certification and Survey Provider Enhanced Reports review, American Association of Bioanalysts-Medical Laboratory Evaluation proficiency testing record review, and staff interview, the laboratory failed to achieve satisfactory performance</p>

	<p>in proficiency testing for the sub-specialty of bacteriology for three of four consecutive events in 2023-2024 (Event 2-2023, Event 3-2023, and Event 2-2024), resulting in subsequent unsuccessful performance (refer to D2028).</p>
<p>D2028</p>	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Certification and Survey Provider Enhanced Reports (CASPER) review, American Association of Bioanalysts-Medical Laboratory Evaluation proficiency testing record review, and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the sub-specialty of bacteriology in three of four consecutive events in 2023-2024 (Event 2-2023, Event 3-2023, and Event 2-2024), resulting in subsequent unsuccessful performance. Findings include: 1. Review of CASPER Report 155D (individual laboratory proficiency testing scores) on 08/19/24 indicated the laboratory scored the following for the sub-specialty of bacteriology in 2023-2024: Event 2-2023 - 72% Event 3-2023 - 77% Event 2-2024 - 57% 2. Review of 2023-2024 American Association of Bioanalysts-Medical Laboratory Evaluation proficiency testing reports on 09/18/24 for the sub-specialty of bacteriology revealed the following results: Event 2-2023 - 74.3% Antimicrobial susceptibility - 20% Culture ID (identification): Urine Culture - 0% Event 3-2023 - 69.0% Culture ID: Misc (miscellaneous) Cultures - 67% Culture ID: Genital Culture - 0% Event 2-2024 - 57.1% Culture ID: Misc Cultures - 33% Culture ID: Genital Culture - 0% The sub-specialty of bacteriology requires a score of 80% or greater for satisfactory performance. 3. During a telephone interview at 1:10 p.m. on 08/19/24, the laboratory supervisor (#1) confirmed the laboratory had scored less than eighty percent in the sub-specialty of bacteriology for Event 2-2023, Event 3-2023, and Event 2-2024.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on Certification and Survey Provider Enhanced Reports review, American Association of Bioanalysts-Medical Laboratory Evaluation proficiency testing record review, and staff interview, the laboratory director failed to fulfill the responsibility for overall management of the laboratory by failing to ensure successful proficiency testing performance for the sub-specialty of bacteriology in three of four consecutive events in 2023-2024 (Event 2-2023, Event 3-2023, and Event 2-2024) resulting in subsequent unsuccessful participation in proficiency testing (refer to D6089).</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p>

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on Certification and Survey Provider Enhanced Reports review, American Association of Bioanalysts-Medical Laboratory Evaluation proficiency testing record review, and staff interview, the laboratory director failed to ensure successful participation in proficiency testing for the sub-specialty of bacteriology in three of four consecutive events in 2023-2024 (Event 2-2023, Event 3-2023, and Event 2-2024), resulting in subsequent unsuccessful performance (refer to D2028).