

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408554	(X3) Date Survey Completed 07/26/2022
Name of Provider or Supplier Pembina County Memorial Hospital	Street Address, City, State 301 Mountain St E, Cavalier, 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	<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 Wisconsin State Laboratory of Hygiene and American Proficiency Institute proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte Digoxin for three of four consecutive events in 2021 (Events 2 and 3) and 2022 (Event 2), resulting in subsequent unsuccessful performance. (Refer to D2118)</p>
D2118	<p>TOXICOLOGY CFR(s): 493.845(f)</p>

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 Digoxin in three of four consecutive events in 2021 (Events 2 and 3) and 2022 (Event 2), resulting in subsequent unsuccessful performance. Findings include: 1. Review of 2021 Wisconsin State Laboratory of Hygiene (WSLH) and 2022 American Proficiency Institute (API) proficiency testing reports on 07/26/22 for the analyte Digoxin revealed the following results: WSLH Event 2-2021 - 60% Sample Lab Results Acceptable Range #6 1.0 0.4 - 0.8 #7 1.2 0.7 - 1.1 #8 1.7 1.1 - 1.7 #9 1.5 1.0 - 1.6 #10 1.9 1.4 - 2.0 WSLH Event 3-2021 - 60% Sample Lab Results Acceptable Range #11 2.0 1.3 - 1.9 #12 1.2 1.0 - 1.6 #13 0.9 0.4 - 0.8 #14 1.0 0.7 - 1.1 #15 1.6 1.1 - 1.7 API Event 2-2022 - 60% Sample Lab Results Acceptable Range #6 1.4 1.1 - 1.8 #7 0.7 0.3 - 0.8 #8 3.4 0.8 - 1.3 #9 2.2 0.6 - 1.0 #10 1.3 1.0 - 1.7 The subspecialty of toxicology requires a score of 80% or greater for satisfactory performance. 2. During a telephone interview at 12:05 p.m. on 07/26/22, the laboratory manager (#1) stated the laboratory had scored less than 80% for Digoxin in Events 2 and 3 in 2021 and Event 2 in 2022.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

Based on Wisconsin State Laboratory of Hygiene and American Proficiency Institute proficiency testing record review and staff interview, the laboratory director failed to fulfill the responsibility for overall operation of the laboratory regarding the maintenance of a quality assessment program to prevent a third out of four (Event 2 in 2022) unsatisfactory proficiency testing result resulting in subsequent unsuccessful participation in proficiency testing (refer to D6094).

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on proficiency testing record review and staff interview, the laboratory director failed to ensure the maintenance of a quality assessment program to help prevent unsatisfactory performance in proficiency testing for the analyte Digoxin for the third event (Event 2 in 2022) in four consecutive events in 2021-2022, resulting in subsequent unsuccessful proficiency testing performance. Findings include: 1. Review

of 2021 Wisconsin State Laboratory of Hygiene (WSLH) and 2022 American Proficiency Institute (API) proficiency testing reports on 07/26/22 for the analyte Digoxin revealed the following results: WSLH Event 2-2021 - 60% Sample Lab Results Acceptable Range #6 1.0 0.4 - 0.8 #7 1.2 0.7 - 1.1 #8 1.7 1.1 - 1.7 #9 1.5 1.0 - 1.6 #10 1.9 1.4 - 2.0 WSLH Event 3-2021 - 60% Sample Lab Results Acceptable Range #11 2.0 1.3 - 1.9 #12 1.2 1.0 - 1.6 #13 0.9 0.4 - 0.8 #14 1.0 0.7 - 1.1 #15 1.6 1.1 - 1.7 API Event 2-2022 - 60% Sample Lab Results Acceptable Range #6 1.4 1.1 - 1.8 #7 0.7 0.3 - 0.8 #8 3.4 0.8 - 1.3 #9 2.2 0.6 - 1.0 #10 1.3 1.0 - 1.7 The subspecialty of toxicology requires a score of 80% or greater for satisfactory performance. 2. During a telephone interview at 12:05 p.m. on 07/26/22, the laboratory manager (#1) stated the laboratory had scored less than 80% for Digoxin in Events 2 and 3 in 2021 and Event 2 in 2022.