

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408554	(X3) Date Survey Completed 07/25/2023
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 American Proficiency Institute proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte creatine kinase for three of four consecutive events in 2022-2023 (Events 2 and 3 in 2022 and Event 2 in 2023) and for the analyte total bilirubin for three consecutive events in 2022-2023 (Event 3 in 2022 and Events 1 and 2 in 2023), resulting in subsequent unsuccessful performance for both analytes (Refer to D2096).</p>
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 creatine kinase for three of four consecutive events in 2022-2023 (Events 2 and 3 in 2022 and Event 2 in 2023) and for the analyte total bilirubin for three consecutive events in 2022-2023 (Event 3 in 2022 and Events 1 and 2 in 2023), resulting in subsequent unsuccessful performance. Findings include: 1. Review of 2022-2023 American Proficiency Institute (API) proficiency testing reports on 07/25/23 for the analytes creatine kinase (CK) and total bilirubin (T Bili) revealed the following results: CK: Event 2-2022 - 20% Sample Lab Results Acceptable Range #06 131 145 - 271 #07 20 15 - 29 #08 109 112 - 209 #09 72 75 - 141 Sample Lab Results Acceptable Range #10 137 142 - 265 CK: Event 3-2022 - 40% Sample Lab Results Acceptable Range #11 61 116 - 217 #12 115 56 - 106 #13 94 97 - 182 #14 172 160 - 299 #15 142 133 - 248 CK: Event 2-2023 - 40% Sample Lab Results Acceptable Range #06 78 77 - 145 #07 132 147 - 275 #08 40 41 - 78 #09 189 175 - 327 #10 125 127 - 237 T Bili: Event 3-2022 - 60% Sample Lab Results Acceptable Range #11 0.8 2.2 - 3.4 #12 2.4 0.4 - 1.3 #13 1.7 1.7 - 2.7 #14 4.3 3.6 - 5.6 #15 3.1 2.7 - 4.2 T Bili: Event 1-2023 - 40% Sample Lab Results Acceptable Range #01 0.2 0.2 - 1.1 #02 0.1 0.0 - 0.5 #03 2.9 3.2 - 5.0 #04 0.2 0.6 - 1.5 #05 1.9 2.2 - 3.4 T Bili: Event 2-2023 - 60% Sample Lab Results Acceptable Range #06 0.8 0.7 - 1.6 Sample Lab Results Acceptable Range #07 2.0 2.5 - 3.8 #08 0.2 0.0 - 0.8 #09 3.4 3.4 - 5.8 #10 1.8 2.0 - 3.1 The specialty of chemistry requires a score of 80% or greater for satisfactory performance. 2. During a telephone interview at 1:40 p. m. on 07/25/23, the laboratory manager (#1) stated the laboratory had scored less than 80% for CK in Events 2 and 3 in 2023 and Event 2 in 2023; and for total bilirubin in Event 3 in 2022 and Events 1 and 2 in 2023.

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 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 for creatine kinase and a third consecutive (Event 2 in 2023) unsatisfactory proficiency testing result for total bilirubin resulting in subsequent unsuccessful participation in proficiency testing for both analytes (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 creatine kinase for the third event (Event 2 in 2023) in four consecutive events and for the analyte total bilirubin for the third consecutive event (Event 2 in 2023) in 2022-2023, resulting in subsequent unsuccessful proficiency testing performance for both analytes. Findings include: 1. Review of 2022-2023 American Proficiency Institute (API) proficiency testing reports on 07/25/23 for the analytes creatine kinase (CK) and total bilirubin (T Bili) revealed the following results: CK: Event 2-2022 - 20% Sample Lab Results Acceptable Range #06 131 145 - 271 #07 20 15 - 29 #08 109 112 - 209 #09 72 75 - 141 #10 137 142 - 265 CK: Event 3-2022 - 40% Sample Lab Results Acceptable Range #11 61 116 - 217 Sample Lab Results Acceptable Range #12 115 56 - 106 #13 94 97 - 182 #14 172 160 - 299 #15 142 133 - 248 CK: Event 2-2023 - 40% Sample Lab Results Acceptable Range #06 78 77 - 145 #07 132 147 - 275 #08 40 41 - 78 #09 189 175 - 327 #10 125 127 - 237 T Bili: Event 3-2022 - 60% Sample Lab Results Acceptable Range #11 0.8 2.2 - 3.4 #12 2.4 0.4 - 1.3 #13 1.7 1.7 - 2.7 #14 4.3 3.6 - 5.6 #15 3.1 2.7 - 4.2 T Bili: Event 1-2023 - 40% Sample Lab Results Acceptable Range #01 0.2 0.2 - 1.1 #02 0.1 0.0 - 0.5 #03 2.9 3.2 - 5.0 #04 0.2 0.6 - 1.5 #05 1.9 2.2 - 3.4 T Bili: Event 2-2023 - 60% Sample Lab Results Acceptable Range #06 0.8 0.7 - 1.6 #07 2.0 2.5 - 3.8 #08 0.2 0.0 - 0.8 #09 3.4 3.4 - 5.8 #10 1.8 2.0 - 3.1 The specialty of chemistry requires a score of 80% or greater for satisfactory performance. 2. During a telephone interview at 1:40 p.m. on 07/25/23, the laboratory manager (#1) stated the laboratory had scored less than 80% for CK in Events 2 and 3 in 2023 and Event 2 in 2023; and for total bilirubin in Event 3 in 2022 and Events 1 and 2 in 2023.