

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408554	(X3) Date Survey Completed 11/28/2022
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 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 two consecutive events in 2022 (Events 2 and 3) and for the analyte lactate dehydrogenase for two of three consecutive events in 2022 (Events 1 and 3), resulting in unsuccessful performance for both analytes. (Refer to D2096)</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 creatine kinase (CK) for two consecutive events in 2022 (Events 2 and 3) and for the analyte lactate dehydrogenase (LD) for two of three consecutive events in 2022 (Events 1 and 3), resulting in unsuccessful performance for both analytes. Findings include: 1. Review of 2022 American Proficiency Institute (API) proficiency testing reports on 11/28/22 for the analytes CK and LD 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 #12 115 56 - 106 #13 94 97 - 182 #14 172 160 - 299 #15 142 133 - 248 LD: Event 1-2022 - 0% Sample Lab Results Acceptable Range #01 326 129 - 194 #02 1978 665 - 983 #03 386 159 - 240 #04 1312 478 - 718 #05 741 281 - 422 LD: Event 3-2022 - 60% Sample Lab Results Acceptable Range #11 345 479 - 720 #12 577 264 - 398 #13 514 413 - 620 #14 820 680 - 1021 #15 694 555 - 833 The specialty of chemistry requires a score of 80% or greater for satisfactory performance. 2. During a telephone interview at 10:55 a.m. on 11/28/22, the laboratory manager (#1) confirmed the laboratory had scored less than 80% in Events 2 and 3 in 2022 for CK and in Events 1 and 3 in 2022 for LD.