

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  35D0408554	<b>(X3) Date Survey Completed</b>  10/21/2024
<b>Name of Provider or Supplier</b>  Pembina County Memorial Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing desk review conducted on October 21, 2024 found the laboratory out of compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 493.1780. A condition level deficiency was cited at 42 CFR 493.803 Condition: Successful Participation.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 Proficiency Institute proficiency testing record review, and staff interview, the</p>

laboratory failed to achieve satisfactory performance in proficiency testing for the analyte creatine kinase (CK) for two of three consecutive events in 2024 (Event 2 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 Certification and Survey Provider Enhanced Reports (CASPER) review, 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 of three consecutive events in 2024 (Event 2 and Event 3) resulting in unsuccessful performance. Findings include: 1. Review of CASPER Report 155D (individual laboratory proficiency testing scores) on 10/18/24 indicated the laboratory scored the following for the analyte CK in 2024: Event 2 - 20% Event 3 - 40% 2. Review of 2024 American Proficiency Institute (API) proficiency testing reports on 10/18/24 for the analyte CK revealed the following results: Event 2-2024 - 20% Sample Lab Results Acceptable Range #06 135 139 - 259 #07 77 86 - 161 #09 56 69 - 130 #10 20 32 - 61 Event 3-2022 - 40% Sample Lab Results Acceptable Range #12 22 37 - 71 #13 58 68 - 127 #15 90 95 - 179 The specialty of chemistry requires a score of 80% or greater for satisfactory performance. 3. During a telephone interview at 11:35 a.m. on 10/21/24, the laboratory manager (#1) confirmed the laboratory had scored less than 80% for CK in Events 2 and 3 in 2024.