

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408554	(X3) Date Survey Completed 08/15/2024
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 proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte partial pressure of carbon dioxide (pCO2) for two of three consecutive events in 2023-2024 (Event 3-2023 and Event 2-2024), resulting in unsuccessful performance (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 partial pressure of carbon dioxide (pCO₂) for two of three consecutive events in 2023-2024 (Event 3-2023 and Event 2-2024), resulting in unsuccessful performance. Findings include: 1. Review of 2023-2024 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing reports on 08/14/24 for the analyte pCO₂ revealed the following results: pCO₂: Event 3-2023 - 0% Sample Lab Results #11 no results submitted #12 no results submitted #13 no results submitted #14 no results submitted #15 no results submitted pCO₂: Event 2-2024 - 60% Sample Lab Results Acceptable Range #06 31 26 - 36 #07 61 64 - 75 Sample Lab Results Acceptable Range #08 49 48 - 58 #09 43 40 - 50 #10 59 60 - 70 The specialty of chemistry requires a score of 80% or greater for satisfactory performance. 2. During interview at 5:00 p.m. on 08/14/24, the laboratory manager (#1) confirmed the laboratory had failed to submit proficiency testing results for pCO₂ in Event 3-2023 and scored 60% for pCO₂ in Event 2-2024.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on policy review, record review, and staff interview, the laboratory failed to perform quality control (QC) as stated in their policy for 3 of 3 analytes (troponin, creatine kinase-myocardial band [CK-MB], and myoglobin) with individualized quality control plans (IQCPs) in 2024. The laboratory performed 190 troponin, 152 CK-MB, and 28 myoglobin patient tests during the timeframes when the laboratory failed to perform monthly QC. Findings include: 1. Reviewed on 08/15/24, the policy "IQCP for Biosite Triage," 07/14/16, stated, ". . . Final QCP [quality control plan] for Biosite Triage . . . Test System: Biosite Triage (Troponin, CK-MB, Myoglobin) . . . Based on the IQCP, assessment we feel that monthly QC or with each new shipment, whichever is more frequent will be satisfactory for our facility. . . ." 2. Review of the 2024 QC results for the analytes troponin, CK-MB, and myoglobin on the Triage Meter Pro analyzer occurred on 08/15/24. The laboratory failed to perform two levels of QC for the following: - March: QC not performed from 02/15/24 through 04/11/24 (56 days) - June: QC not performed from 05/19/24 through 07/27/24 (68 days) 3. During interview at 10:50 a.m. on 08/15/24, the laboratory manager (#1) stated the laboratory should perform QC each month for the Triage analyzer tests and confirmed the laboratory failed to perform monthly QC in March and June 2024.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to perform two levels of quality control (QC) 6 of 31 days (May 9 - 14) for the analyte chloride in May 2024. The laboratory performed 83 chloride patient tests in May 2024 when the laboratory failed to perform QC. Findings include: 1. Review of the May 2024 QC records for the analyte chloride on the Ortho Vitros chemistry analyzer occurred on 08/15/24. The laboratory failed to perform two levels of QC May 9 - 14. 2. During interview at 11:50 a.m. on 08/15/24, the laboratory manager (#1) stated the laboratory should perform QC each day of patient testing and confirmed the laboratory failed to perform chloride QC May 9 - 14. 3. Reviewed on 08/15/24, the policy "Quality Control Frequency and QC Material," effective 04/16/19, stated, "Purpose: This protocol applies to all laboratory specialties and subspecialties performed at PCMH [Pembina County Memorial Hospital]. . . . all areas of the laboratory must be monitored with the use of at least 2 levels of quality control material. . . . The following information identifies the frequency of control . . . Chemistry: J&J Vitros 350 Once daily . . ."

D5451

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(iii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, policy and procedure review, and staff interview, the laboratory failed to ensure performance of blood type and antibody detection quality control (QC) testing 1 of 4 immunohematology patient testing days (04/29/24) in April 2024. The laboratory performed blood type and antibody detection testing for one patient on 04/29/24. Findings include: 1. Reviewed at 7:35 a.m. on 08/15/24, the April 2024 immunohematology patient testing and QC records indicated the laboratory performed blood type and antibody detection patient testing on 04/29/24 for Patient #1185605 and failed to perform QC. 2. Review of the following policies and procedures occurred on 08/15/24: - "Quality Control Frequency and QC Material," effective 04/16/19, stated, "Purpose: This protocol applies to all laboratory specialties and subspecialties performed at PCMH [Pembina County Memorial Hospital]. . . . all areas of the laboratory must be monitored with the use of at least 2 levels of quality control material. . . . The following information identifies the frequency of control . . . Blood Bank Each day of testing . . ." - "ABO [blood group

antigens] and RH [sic] [Rhesus blood factor] Testing Patient Samples Using MTS [Micro Typing System] Gel Method," effective 02/07/11, stated, ". . . Quality Control: Quality control will be performed each day (24 hours) patient samples are to be tested. . . ." - "Gel IGG [sic] [Immunoglobulin G] Antibody Screen Testing," effective 02/07/11, stated, "Quality Control: 1. Gel Card - To confirm the specificity and reactivity . . . each lot is tested on each day of use . . ." 3. During interview at 8:35 a.m. on 08/15/24, the laboratory manager (#1) confirmed the laboratory should perform quality control each day of patient testing and the laboratory did not document performance of blood type and antibody screen QC on 04/29/24.

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 proficiency testing record review, record review, policy and procedure review, and staff interview, the laboratory director failed to fulfill the responsibility for overall operation of the laboratory regarding the maintenance of quality control (refer to D6093) and quality assessment programs (refer to D6094).

D6093

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

The laboratory director must ensure that the quality control 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 record review, policy and procedure review, and staff interview, the laboratory director failed to ensure the maintenance of a quality control (QC) program to identify quality failures and ensure quality laboratory results (refer to D5445, D5447, and D5451). Findings include: 1. The laboratory failed to perform monthly QC as stated in their policy for the analytes troponin, creatine kinase-myocardial band, and myoglobin with individualized quality control plans in March and June 2024 (refer to D5445). 2. The laboratory failed to perform two levels of QC six days in May 2024 for the analyte chloride (refer to D5447). 3. The laboratory failed to perform blood type and antibody detection QC testing one immunohematology patient testing day in April 2024 (refer to D5451).

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 ensure satisfactory performance in proficiency testing (refer to D2096). Findings include: 1. The laboratory failed to achieve satisfactory performance in proficiency testing for the analyte partial pressure of carbon dioxide in Event 3-2023 and Event 2-2024 resulting in unsuccessful performance (refer to D2096).