Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408732	05/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Jamestown Regional Medical Center	2422 20th St Sw, Jamestown, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to verify the accuracy of results for 11 of 11 (1st Event, 2nd Event, and 3rd Event Chemistry Core; 1st Event, 2nd Event, and 3rd Event Hematology/Coagulation; 1st Event, 2nd Event, and 3rd Event Immunology/Immunohematology; and 1st Event and 2nd Event Chemistry - Miscellaneous) verification events in 2025. The laboratory performed 183 blood gas (pH [potential of hydrogen, scale used to measure acidity or alkalinity], PO2 [partial pressure of oxygen, a measure of the amount of dissolved oxygen gas], and PCO2 [partial pressure of carbon dioxide]) and 77 lactate patient tests on the iSTAT; 280 glucose, 279 BUN (Blood Urea Nitrogen), 282 creatinine, 283 sodium, 286 potassium, 279 chloride, 279 CO2 (Carbon Dioxide), 279 calcium, 240 total protein, 240 albumin, 240 ALP (Alkaline Phosphatase), 240 AST (Aspartate Aminotransferase), 240 ALT (Alanine Aminotransferase), 241 total bilirubin, 118 CRP (C-Reactive Protein), and 17 amylase patient tests on the Piccolo; 362 HCG (Human Chorionic Gonadotropin) on the Roche Cobas 6000; 8 CBC (Complete Blood Count) with no differential, 3 hemoglobin, and 1 hematocrit patient tests on the Sysmex pocH 100i; and 139 ABO blood group, 139 Rh factor, and 38 antibody screen patient tests from 04/15/25 through 04/14/26. Findings include: 1. Reviewed on 05/12 /26, the 1st Event 2025, 2nd Event 2025, and 3rd Event 2025 verification proficiency testing records failed to show the laboratory documented verification of accuracy of blood gas, lactate, glucose, BUN, creatinine, sodium, potassium, chloride, CO2, calcium, total protein, albumin, ALP, AST, ALT, total bilirubin, CRP, amylase, HCG, CBC with no differential, hemoglobin, hematocrit, ABO blood group, Rh factor, and antibody screen. 2. During interview the morning of 05/12/26, a General Supervisor (#1) confirmed the laboratory failed to document review of the 1st Event 2025, 2nd

	Event 2025, and 3rd Event 2025 Chemistry Core Verification; 1st Event, 2nd Event, and 3rd Event Hematology/Coagulation Verification; 1st Event, 2nd Event, and 3rd Event Immunology/Immunohematology Verification; and 1st Event and 2nd Event Chemistry - Miscellaneous Verification in 2025. 3. Reviewed on 05/12/26, the policy ". . . Proficiency Testing Programs," dated 10/22/25, stated, "The manager reviews and signs the Performance Summary EXCEPT Immunohematology. . . . The Performance Summary of all Immunohematology testing will be forwarded to the medical director to sign."
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure review, the laboratory failed to verify calibration at least every six months for 1 of 59 analytes (urine BUN [blood urea nitrogen]) calibrated with less than three calibrator levels on the Cobas 6000 in 2025. The laboratory performed six urine BUN patient tests from 04/15/25 through 04/14/26. Findings include: 1. Reviewed on 05/13/26, the 2025 urine BUN calibration records indicated the use of two levels of calibrators for calibration of urine BUN. 2. Reviewed on 05/13/26, the 2025 calibration verification records failed to include urine BUN calibration verification in October 2025. 3. Upon request on 05 /13/26, the laboratory failed to provide evidence of calibration verification at least twice annually for urine BUN in 2025. 4. During interview at 11:53 a.m. on 05/13/26, a General Supervisor (#1) confirmed the laboratory had failed to verify calibration at least twice annually for urine BUN in 2025. 5. Reviewed on 05/13/26, the policy ". . . Cobas 6000," dated 12/01/25, stated, "6 Month Maintenance . . . Calibration Verification . . . Calibration verification needs to be performed on [sic] every 6 months on analytes that perform less than a 2 point calibration."
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

	using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to include external quality control (QC) requirements in an Individualized Quality Control Plan (IQCP) that monitors accuracy and precision for 1 of 14 test systems (iSTAT) with IQCPs reviewed. The laboratory performed 183 blood gas (pH [potential of hydrogen, scale used to measure acidity or alkalinity], PO2 [partial pressure of oxygen, a measure of the amount of dissolved oxygen gas], and PCO2 [partial pressure of carbon dioxide]) patient tests from 04/15/25 through 04/14/26. Findings include: 1. Reviewed at approximately 10:30 a.m. on 05/13/26, the JRMC (Jamestown Regional Medical Center) iSTAT Blood Gas IQCP failed to identify external quality control (QC) requirements. 2. During an interview the morning of 05 /13/26, a General Supervisor (#1) confirmed the laboratory failed to document external QC requirements in the iSTAT Blood Gas IQCP. 3. Reviewed at 10:50 a.m. on 05/13/26, the policy ". . . IQCP," dated 01/08/26, stated, ". . . the number, type (external or internal quality control) and frequency must be established. Frequency of QC must meet or exceed manufacturer's recommendations. . . ."
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory director failed to ensure 2 of 2 new testing personnel in 2025 (Testing Personnel #2 and #3) received appropriate training and demonstrated reliable performance of all testing operations before reporting patient results. Findings include: 1. Reviewed at approximately 8:00 a.m. on 05/13/26, the 2025 testing personnel records failed to include documentation ensuring complete training and demonstration of reliable performance of all testing operations before reporting patient results for Testing Personnel #2 and #3. 2. Reviewed at approximately 8:15 a.m. on 05/13/26, the 2025 testing personnel records showed Testing Personnel (#2) started patient testing February 2025 and Testing Personnel (#3) started March 2025. 3. During an interview at 8:21 a.m. on 05/13/26, a General Supervisor (#1) confirmed the laboratory did not have documented maintenance and quality control performance of Cepheid GeneXpert training for Testing Personnel (#2) and Radiometer ABL90 training for Testing Personnel (#3). 4. Reviewed at 10:50 a.m. on 05/13/26, the policy ". . . Competency Assessment of Laboratory Personnel," dated 04/16/25, stated, "A. Training . . . 3. New hires must demonstrate satisfactory performance before they are allowed to perform tasks independently. . . ." 5. During an interview the morning of 05 /13/26, a General Supervisor (#1) confirmed Testing Personnel (#2) performed 10

	tests on the Cepheid GeneXpert and five tests on the Radiometer ABL90 between February 2025 and September 2025 and Testing Personnel (#3) performed 15 tests on the Cepheid GeneXpert and nine tests on the Radiometer ABL90 between March 2025 and September 2025.