Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2175063	06/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
St Peters Health	515 South Front St, Townsend, MT	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of chemistry and hematology procedures, the laboratory failed to verify chemistry and blood gas reference intervals (normal values) are appropriate for the laboratory's patient population (refer to D5421); and failed to perform at least a three-point calibration verification every six months (refer to D5439); failed to include the number, type, and frequency of testing for the i-STAT external electronic simulator in the Individual Quality Control Plan (IQCP) (refer to D5441); and failed to perform two levels of external quality controls as per their IQCP (refer to D5445).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review, patient results reports, and interview with the technical consultant (TC) # 1, the laboratory failed to verify that the reference intervals (normal values) are appropriate for the laboratory's patient population for Chem8+ and CG4+ cartridges performed on the i-STAT analyzer from June 17, 2020 to June 22, 2022. Findings: 1. Review of three of three patient results reports for chemistry, blood gas with lactate listed reference ranges for analytes: creatinine, BUN, glucose, sodium, potassium, chloride, ionized calcium, TCO2, hemoglobin, hematocrit, pH, PO2, PCO2, HCO3, Base Excess, O2 saturation, and lactate. 2. Review of Intended For Use (IFU) for i-STAT CG4+ Cartridge and i-STAT CHEM8+ Cartridge revealed the reference range values differed from the patient results report's reference range values. 3. The review of the laboratory's i-STAT Point of Care Testing Procedure lacked reference intervals (normal values). 4. No patient population studies to support the reference ranges listed in the "POC CHEM 8 PLUS" and "POC BLOOD GAS W /LAC" patient results reports were available for review. 5, An interview with TC # 1 on June 22, 2022 at 10:00 AM confirmed these findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of i-STAT calibration records and interview with the Testing Consultant (TC) #1, the laboratory failed to perform at least a three-point (a minimal, mid-point, and maximum) calibration verification every six months or after CLEW software updates from January 1, 2020 to June 22, 2022. Findings: 1. Review of calibration records for CHEM 8+ and CG4+ cartridges performed on the Abbott i-STAT analyzer for analytes: sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide, pH, PCO2 and PO2, lacked documentation of a calibration verification including, at least, a minimal, midpoint, and maximum value for each analyte performed every six months or after CLEW software updates from January 1, 2020 to June 22, 2022. 2. Review of the test

	volume report dated 5/18/22 revealed one blood gas (CG4+) patient and five chemistry (CHEM 8+) patients were tested from May 18, 2021 to May 18, 2022. 3. Review of Point of Care Testing Procedure i-STAT and IQCP lacked instruction for Calibration and Calibration Verification. 4. Interview with the TC #1 on June 22, 2022, at 12:30 PM, confirmed the laboratory failed to perform at least a three-point calibration verification for analytes performed on the i-STAT analyzer every six months or after CLEW software updates from January 1, 2020 to June 22, 2022.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of procedures, and interview with Technical Consultant (TC) #1, the laboratory failed to include the number, type, and frequency of testing for the external electronic simulator for the i-STAT Individual Quality Control Plan (IQCP) from January 1, 2020 to June 22, 2022 . Findings: 1. The laboratory's i-STAT Point of Care Testing Procedure and i-STAT IQCP failed to include instructions for the external electronic simulator. 2. Review of Abbott's i-STAT 1 System Manual revealed that the laboratory failed to verify the thermal probe checks with the external electronic simulator every six months. 3. No documentation of external electronic simulator checks were available for review. 4. Interview with the TC #1 on June 22, 2022 at 11:50 AM confirmed these findings.
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 record review, procedures, and interview with the technical consultant (TC) #1, the laboratory failed to perform two levels of external quality controls (QC) on CHEM 8+, CG4+ and PT/INR cartridges as per their laboratory procedure from December 1, 2021 to April 30, 2022. Findings: 1. Review of the i-STAT Point of Care

	Testing Procedure and the CoaguChek XS Pro PT/INR Point of Care Testing Procedure revealed, "Liquid Quality Control Material (normal and abnormal) is used when each new lot or shipment of cartridge is put into use." 2. Review of i-STAT1 Quality Control Plan and CoaguChek Quality Control Plan revealed, "External Controls: Two levels of control material are run monthly or upon start of a new lot of reagents." 3. A review quality control logs for the i-STAT and CoaguChek lacked documentation of two levels of external liquid QC checks from December 1, 2021 to April 30, 2022. 4. Interview with the TC #1 on June 5, 2022, at 11:40 AM, confirmed the laboratory failed to perform either monthly QC or QC on new lot or shipment of cartridges before being put into use from December 1, 2021 to April 30, 2022.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . THIS IS A REPEAT DEFICIENCY Based on review of patient results reports and interview with the Technical Consultant (TC) # 1, the laboratory failed to include the testing facility's name and address on the patient results report. Findings: 1. Review of three of four patient results reports lacked the testing facility's (St. Peters Health in Townsend) name and address on the report. 2. Interview with TC #1 on June 22, 2022, at 11:30 PM, confirmed the laboratory reports failed to include the testing facility's name and address.