Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410407	06/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
St Peters Health	2475 Broadway, Helena, 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 record review of chemistry, hematology, molecular, laboratory procedures and product inserts, the laboratory failed to verify the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population for complete blood counts (refer to D5421); failed to perform calibration verification for the i-STAT analyzers (refer to D5439); failed to follow manufacturer's instructions for the number, type, and frequency of the external controls for ePlex Respiratory Pathogen Panel 2 (refer to D5445); and failed to evaluate and define twice a year the relationship between test results using different methodologies or instruments (refer to D5775).
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 supervisor (TS) #8, the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for complete blood counts (CBC) with differential performed on the Sysmex XN 9000 hematology analyzer. Findings: 1. A review of CBC Auto Diff patient results report 0310:H00001R listed reference ranges for the following analytes: Red blood cell count (RBC), White blood cell count (WBC), Platelet count, Hemoglobin (Hgb), Hematocrit (Hct), Mean corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH), Mean corpuscular hemoglobin concentration (MCHC), Red cell distribution width (RDW), Mean platelet volume (MPV), Reticulocyte count, WBC (white blood cell) differential, including Neutrophil Percent (NEUT%), Neutrophil number (NEUT#), Lymphocyte Percent (LYMPH%), Lymphocyte Number (LYMPH#), Monocyte Percent (MONO%), Monocyte Number (MONO#), Eosinophil Percent (EOS%), Eosinophil Number (EOS#), Basophil Percent (BASO%), Basophil Number (BASO#), Immature Granulocyte Number (IG#) and Immature Granulocyte Percent (IG%) 2. No patient population studies to support the reference ranges listed in the CBC Auto Diff patient results report were available for review. 3. Interview with the TS #8 on June 15, 2022, at 11:30 AM, confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for complete blood counts (CBC) with differential performed on the Sysmex XN 9000 hematology analyzer.
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 calibration records for the Abbott i-STAT Analyzers using CHEM 8+ and CG4+, cartridges for analytes sodium, potassium, chloride, ionized calcium,

	glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide, pH, PCO2 and PO2, and interview with the Testing Supervisor (TS) #9, 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 16, 2022. Findings: 1. Review of calibration records for Abbott i-STAT analyzer 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 15, 2022. 2. Review of Point of Care Testing Procedure i-STAT and IQCP lacked instruction for Calibration and Calibration Verification. 3. Interview with the TS #9 on June 16, 2022, at 9:30 AM, 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 16, 2022.
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, product inserts, procedures and interview with the technical supervisor (TS) #2, the laboratory failed to follow manufacture's instruction and include in their IQCP the number, type and frequency of external controls for the ePlex Respiratory Pathogen Panel 2 (RP2) nucleic acid multiplex diagnostic test intended for use on the GenMark Dx ePlex Instrument from November 18, 2020 to June 15, 2022. Findings: 1. Review of RP2 external controls records for patient testing revealed ePlex RP2 Positive A and ePlex RP2 Positive B being rotated every other month, new shipment or lot number. 2. Review of ePlex RP2 Control M451 product insert revealed: a. ePlex RP2 Control M451 is composed of 3 controls: ePlex RP2 Positive A, ePlex RP2 Positive B and ePlex RP2 Negative. b. INTENDED USE: The ePlex RP2 Control M451 is intended for use as an external positive and negative quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of pathogens ... RP2 Control M451 is composed of synthetic DNA and RNA specifically designed for and intended to be used solely with the ePlex RP2 Panel on the ePlex System. 3. Review of ePlex Respiratory Pathogen Panel 2 Package Insert revealed, "B. Authorized laboratories using the ePlex RP2 Panel will use the ePlex RP2 Panel as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the ePlex RP2 Panel are not permitted." 4. Review of St Peter's Hospital Laboratory Internal Quality Control Plan (IQCP) for Test System: GenMark Dx ePlex Respiratory Panel 2 revealed, "The frequency of External Control testing has been established using the Individualized Quality Control Plan (IQCP), and reflects the requirements listed in the package insert." 5. Interview with the TS #1

	on June 15, 2022, at 5:00 PM, confirmed the laboratory failed to follow manufacture's instruction and include in their IQCP the number, type and frequency of external controls for the ePlex RP2 Panel intended for use on the GenMark Dx ePlex Instrument from November 18, 2020 to June 15, 2022.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review of College of American Pathologists (CAP) Proficiency Testing (PT) instrument comparison studies, procedure, and interview with Technical Supervisor (TS) # 9, the laboratory failed to evaluate and define twice a year the relationship between test results using different methodologies or instruments, to include comparison of six out of six Abbott i-STAT analyzers to each other and comparison of Abbott i-STAT with Siemens Dimension Vista (chemistry analytes), Siemens Rapid Point 500 (blood gas analytes), and Sysmex 5100 (coagulation analytes) from January 1, 2020 to June 16, 2022. Findings: 1. Review of CAP chemistry comparison studies lacked instrument comparison studies between the Siemens Dimension Vista and Abbott i-STAT for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide. 2. Review of CAP chemistry comparison studies lacked instrument comparison between Siemens Rapid Point 500 and Abbott i-STAT for analytes lactate, pH, PCO2, and PO2. 3. No instrument comparison studies for Sysmex 5100 and Abbott i-STAT for analytes Prothrombin Time and International Normalized Ratio (PT/INR) were available to review. 4. Review of Point of Care Testing Procedure i-STAT lacked comparison studies parameters and instructions. 5. Interview with TS #9 on June 16, 2022 at 9:40 AM, confirmed the above findings.