Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0992022	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
St Peters Health	2550 East Broadway St, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of annual competency files and an interview with the technical consultant (TC) #2, the laboratory failed to follow their procedure and assess six out of eleven employee's competencies from February 22, 2022, to February 22, 2024. Findings: 1. A review of personnel records lacked documentation of either semiannually competency during the 1st year of patient testing or annual competency of testing personnel for six out of eleven testing personnel (TP#4, TP#5, TP#6, TP#7, TP#8, and TP#9) listed on the CMS Form 209. 2. An interview on February 22, 2024, at 9:25 AM with TC #2, confirmed the lack of competency assessment documentation for six out of eleven testing personnel listed on the CMS Form 209 from February 22, 2022, to February 22, 2024.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on observation, procedures, and an interview with technical consultant (TC) #2, the laboratory failed to follow their written procedures to label two out of two patient specimens with eithervtwo identifiers or a patient label on February 22, 2024. Findings: 1. Observed on February 22, 2024, at 12:00 PM, unlabeled patient specimens next to the Clinitek Status in Pod 1B and again in Pod 2B; for each location, the patient specimen lacked a patient label or two patient identifiers. 2. A review of the "Urine Specimen Collection and POCT Urinalysis" procedure revealed laboratory staff failed to maintain "2 patient ID ' s" or a patient's label on collected specimens throughout the testing process. 3. An interview with TC #2 on February 22, 2024, at 12:15 PM confirmed the laboratory staff failed to label two out of two patient specimens with either a patient label or two identifiers on February 22, 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of records, and interview with technical consultant (TC) #2, the laboratory failed to monitor the temperature of one refrigerator storing quality control (QC) material located in Pod 2B from February 22, 2022, to February 22, 2024. Findings: 1. Observed on February 22, 2024, at 12:15 PM, one out of one refrigerator in Pod 2B contained two sets of (qUAntify Plus Control Normal Level 1 and Abnormal Level 2) QC material performed on the Clinitek Status urine chemistry analyzer. 2. No temperature logs for Pod 2B ' s refrigerator were available for review. 3. Interview with TC #2 on February 22, 2024, at 12:15 PM confirmed Pod 2B laboratory staff were not monitoring the temperature of one out of one refrigerator containing urine quality controls.
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 a review of quality control (QC) records, laboratory procedure, and an interview with the technical consultant (TC #2), the laboratory failed to perform two

	levels of external quality controls (QC) at the frequency dictated by their procedure for prothrombin time performed on the CoaguChek XS Pro from February 22, 2022, to February 22, 2024. Findings: 1. A review of prothrombin time QC records revealed the laboratory staff failed to perform their monthly external QC for the months of September 2022, November 2022, January 2023, February 2023, and March 2023 per their "Quality Control Plan: Coaguchek" procedure. 2. An interview with TC #2 on February 22, 2024, at 11:15 PM confirmed the laboratory failed to perform two levels of external QC for five out of 24 months for prothrombin time performed on the CoaguChek XS Pro from February 22, 2022, to February 22, 2024.