

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2175063	(X3) Date Survey Completed 09/22/2020
Name of Provider or Supplier St Peters Health	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow policies and procedures to assess personnel competency of the Technical Consultant (one of one). Findings: 1. Review of personnel competency evaluations revealed that the Technical Consultant (TC#1) lacked documentation for training and competency. 2. Review of two laboratory IQCP Quality Control Plan for Coagucheck and i-STAT revealed "Non-waived testing: Training will be annually by Healthstream, running of quality controls and six levels of competency bi-annually for the first year and annually thereafter with documentation on file". 3. Confirmed during interview with the Technical Consultant (TC #1) and Laboratory Services Operations Manager (LSOM #1) the laboratory failed to perform training and competency evaluation for TC #1 for specialties Hematology and Routine Chemistry platforms, on 9/22/20 at 12:04 PM.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedures lacked St Peters Health, Townsend's current laboratory director's (LD) signature and date for approval</p>

	<p>prior to patient testing. Findings: 1. Review of procedure manuals revealed the lack of Townsend's Laboratory Director's approval. 2. Review of "Ordering and Resulting Point of Care Testing" contained the laboratory director signature and date from the St Peters Health, Helena location. 3. Confirmed during interview with TC#1 the report's lack of Townsend's LD signature and date for approval prior to patient testing. 9/22/2020 at 10:05 AM.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory report failed to contain the name and address of the laboratory location where the test was performed. Findings: 1. Review of three out of three laboratory reports lacked the testing facility's (St. Peters Health in Townsend) address on the report. 2. Confirmed during interview with TC#1 and Laboratory Services Operations Manager (LSOM#1) the laboratory reports failed to include the facility's address, on 9/22/20 at 10:48 AM.</p>
<p>D6045</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the TC#1 failed to ensure Testing Personnel (TP#1 and TP#2) received training prior to testing patients' specimens. 1. Review of personnel training evaluations revealed the lack of training records for TP #1 and TP#2. prior to testing patient's specimens. 2. Review of the laboratory IQCP Quality Control Plan: CoaguCheck: revealed: "Quality Assessment Plan: New hires will have to complete Coagu Chek training and competency prior to testing." 3. Review of the laboratory IQCP Quality Control Plan: i-STAT revealed: "Quality Assessment Plan: New hires will have to complete i-STAT training and competency prior to testing." 4. Confirmed during interview with TC# 1, LSOM#1, and LD#1, the laboratory failed to perform training for TP#1 and TP#2 prior to patient's testing, on 9/22/20 at 12:04 PM.</p>