

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652518	(X3) Date Survey Completed 07/25/2023
Name of Provider or Supplier Big Sandy Medical Center	Street Address, City, State 166 Montana Avenue E, Big Sandy, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of coagulation records, procedures, and interview with technical supervisor (TS) #1, the laboratory failed to verify the performance specifications of new lots of Activated Partial Thrombin Time (aPTT) reagents performed on Sysmex CA-660 from July 25, 2021, to July 25, 2023. Findings: 1. A review of coagulation procedure revealed the laboratory failed to have a step-by-step procedure for verifying new lots of Dade Actine FSL aPTT reagent. 2. No crossover studies to verify the performance specifications for new lots of aPTT reagents prior to patient testing were available for review. 3. A review of the test volume sheet revealed 37 aPTT tests were resulted from July 25, 2022, to July 25, 2023 (12-month period). 4. An interview with the TS #1 on July 25, 2023, at 1:04 PM, confirmed the laboratory failed to verify the performance specifications of new lots of Dade Actine FSL aPTT reagents from July 25, 2021, to July 25, 2023.</p>