

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652518	(X3) Date Survey Completed 04/18/2023
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a routine desk audit of CMS-155 reports of proficiency testing (PT) performance, review of American Proficiency Institute (API) records and interview with the technical supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for total bilirubin for two out of three PT events (2022 Event 2 and 2023 Event 1) performed on the Siemens Dimension EXL, resulting in unsuccessful proficiency testing performance. (See D2096)</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) scores and interview with technical supervisor (TS) # 1, the laboratory failed to achieve a score of at least 80% for two out of three consecutive PT events (2022 Event 2 and 2023 Event 1) for total bilirubin.

Findings: 1. A review of the API total bilirubin PT scores revealed that in 2022, Event 2 scored 40% and in 2023, Event 1 scored 40%. 2. An interview with (TS) #1 on April 11, 2023, at 10:34 AM confirmed the failed total bilirubin PT events were due to the lack of QC and Calibration acceptability and monitoring.