

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652518	(X3) Date Survey Completed 11/12/2024
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 review of American Proficiency Institute records and an interview with the laboratory director, the laboratory failed to achieve satisfactory performance for magnesium, total iron binding capacity, and triiodothyronine for two consecutive testing events, resulting in unsuccessful proficiency testing performance. (See D2096 and D2107).</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 American Proficiency Institute (API) proficiency testing (PT) scores and interview with laboratory director (LD) # 1, the laboratory failed to achieve a score of at least 80% for two consecutive PT events (routine chemistry 2024 Events 2 and Event 3) for magnesium (Mg) and total iron binding capacity (TIBC), measured. Findings: 1. A review of API's Routine Chemistry PT scores for Mg revealed that in 2024, Event 2 scored 60% and Event 3 scored 20%. 2. A review of API's Routine Chemistry PT scores for TIBC, measured revealed that in 2024, Event 2 scored 60% and Event 3 scored 60%. 3. An interview with LD #1 on November 12, 2024, at 4:49 PM confirmed the failed PT events were due to results running higher than expected.

D2107

ENDOCRINOLOGY

CFR(s): 493.843(f)

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 American Proficiency Institute (API) proficiency testing (PT) scores and interview with laboratory director (LD) # 1, the laboratory failed to achieve a score of at least 80% for two consecutive PT events (Endocrinology 2024 Events 2 and Event 3) for triiodothyronine (Free T3). Findings: 1. A review of API's Endocrinology PT scores for Free T3 revealed that in 2024, Event 2 scored 40% and Event 3 scored 60%. 2. An interview with LD #1 on November 12, 2024, at 4:49 PM confirmed the failed PT events were due to results running higher than expected.