

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652518	(X3) Date Survey Completed 03/31/2025
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
D0000	A proficiency testing desk review was completed on March 25, 2025. At the time of the desk review, it was determined that the laboratory was not in compliance with all conditions required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). The following condition level deficiencies were cited: 493.803 Condition: Successful participation. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
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 an off-site review of the CMS-155 reports of proficiency testing</p>

	<p>performance, American Proficiency Institute (API) proficiency testing (PT) scores, corresponding laboratory records, and email communication with the laboratory director (LD) #1, the laboratory failed to achieve satisfactory performance for routine chemistry for three consecutive proficiency testing events, resulting in subsequent unsuccessful proficiency testing performance in 2024 and 2025. See D2096</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) scores, laboratory records and email communication with the laboratory director (LD) # 1, the laboratory failed to achieve a score of at least 80% for three consecutive proficiency testing events for magnesium (Mg) in the years 2024 and 2025. Findings: 1. A review of API's Routine Chemistry PT scores and laboratory records for Mg on March 24, 2025, revealed the laboratory failed to achieve a satisfactory performance score of 80% or greater for the following PT events: 2024, Event 2 scored 60% 2024, Event 3 scored 20% 2025, Event 1 scored 60% 2. An email from LD #1 on March 18, 2025, at 3:47 PM confirmed the findings, with the laboratory director self-reporting the third unsuccessful magnesium proficiency testing event.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site review of 2024 and 2025 American Proficiency Institute (API) proficiency testing (PT) scores and corresponding laboratory records, and email communication with the laboratory director (LD) #1, the laboratory director failed to provide overall management and direction for the laboratory to ensure an effective corrective action plan had been implemented to avoid higher than expected Magnesium (Mg) proficiency results and prevent a subsequent unsuccessful proficiency testing event. See D6019</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by: Based on an off-site review of the 2024 and 2025 American Proficiency Institute (API) proficiency testing (PT) scores, corresponding laboratory records, and email</p>

communication with laboratory director (LD) #1, the laboratory director failed to implement an effective corrective action plan to prevent three consecutive unsuccessful Magnesium (Mg) proficiency testing events from May 16, 2024, to March 19, 2025. Findings: 1. A review of the corrective action forms for three Mg PT events (2024, Events 2 and 3, and 2025, Event 1) revealed that the unsuccessful PT results were due to exceeding the acceptable PT expected result. The corrective action taken was to repeat the test; however no additional measures were implemented to prevent additional unsuccessful PT results between May 16, 2024, and March 19, 2025. (Refer to D2096) 2. An email communication with LD #1 on March 18, 2025, at 3:47 PM confirmed the laboratory director failed to implement an effective corrective action plan to prevent three consecutive unsuccessful Mg proficiency testing events from May 16, 2024, to March 19, 2025.