

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D2095592	<b>(X3) Date Survey Completed</b>  07/16/2024
<b>Name of Provider or Supplier</b>  Big Sky Laboratory	<b>Street Address, City, State</b>  2509 7th Ave South Suite C1, Great Falls, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 testing personnel (TP), the laboratory failed to achieve satisfactory performance for Sodium (Na) for two out of three testing events, resulting in unsuccessful proficiency testing performance. (See D2096).</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

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 testing personnel (TP) # 1, the laboratory failed to achieve a score of at least 80% for two out of three PT events (routine chemistry 2023 Event 3 and 2024 Event 2) for sodium (Na). Findings: 1. A review of API's Routine Chemistry PT scores for Na revealed that in 2023, Event 3 scored 60% and 2024 Event 2 scored 0%. 2. An interview with (TP) #1 on July 15, 2024, at 5:58 PM confirmed these findings and the manufacturer is scheduled to perform preventative maintenance.