

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410720	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier Deer Lodge Medical Center	Street Address, City, State 1100 Hollenback Lane, Deer Lodge, 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 routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview with laboratory manager, the laboratory failed to achieve satisfactory performance for compatibility testing for two out of three events (2021 Event 2 and 2022 Event 1), resulting in unsuccessful proficiency testing performance. (Refer to D2181)</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p>

Failure to achieve an overall testing event score of satisfactory for 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 Association of Bioanalysts (AAB) proficiency testing scores and interview with laboratory manager, the laboratory failed to achieve a score of 100% for Compatibility Testing for two out of three events (2021 Event 2 and 2022 Event 1). Findings: 1. Review of CMS-153 Unsuccessful Proficiency Testing Report on 05/11/2022 at 10:00 AM, which included Deer Lodge Medical Center with unsuccessful proficiency testing scores for Compatibility Testing. 2. Review of the CMS-155 Individual Laboratory Profile on 05/12/2022 at 9:59 AM, revealed Compatibility Testing scores for 2021 Event 2 was 80% and 2022 Event 1 was 20%. 3. Interview with laboratory manager on 05/12/2022 at 10:48 AM, confirmed unsuccessful proficiency scores for Compatibility Testing due to the quality of testing material.