

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0672851	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Glendive Medical Center Laboratory	Street Address, City, State 202 Prospect Drive, Glendive, 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 Antibody Detection testing for two out of three events (2020 Event 3 and 2021 Event 2), resulting in unsuccessful proficiency testing performance. See D2170</p>
D2172	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(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 proficiency testing scores from American Proficiency Institute (API) and interview with laboratory manager, the laboratory failed to achieve a score of 80% for Antibody Detection for two of three events (2020 Event 3 and 2021 Event 2). Findings: 1. Review of CMS-153 Unsuccessful Proficiency Testing Report on 09/20/2020 at 1:45 PM, which included Glendive Medical Center with unsuccessful proficiency testing scores for Antibody Detection. 2. Review of the CMS-155 Individual Laboratory Profile on 09/20/2020 at 2:00 PM, revealed Antibody Detection scores from API for 2020 Event 3 was 60% and 2021 Event 2 was 0%. 3. Interview with laboratory manager on 09/20/2021 at 4:20 PM, confirmed unsuccessful proficiency scores for Antibody Detection due to clerical errors and failure to enter results by testing personnel.