

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0672851	(X3) Date Survey Completed 09/13/2022
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 a routine desk audit of CMS-155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for Anti-HIV and HIV-1 p24 Antigen (HV) performed on the Alere Determine (Trademark) HIV-1 /2 Ag/Ab Combo for two of three events (2021 Event 2, and 2022 Event 1), resulting in unsuccessful proficiency testing performance. See D2084.</p>
D2084	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 proficiency testing scores and interview with testing personnel (TP) # 1, the laboratory failed to achieve a score of 80% for Anti-HIV and HIV-1 p24 Antigen (HV) typing for two of three events (2021 Event 2 and 2022 Event 1). Findings: 1. Review of the CMS-155 report on 8/15/2022 at 10:00 AM revealed that the American Proficiency Institute (API) reported Anti-HIV and HIV-1 p24 Antigen (HV) scores for 2021 Event 2 was 0%, and 2022 Event 1 was 40%. 2. An interview with TP#1 on 08/31/2022 at 12:51 PM, confirmed the failed scores were due to late submission and clerical errors.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing scores and interview with testing personnel (TP) # 1, the laboratory director failed to ensure results were submitted within the timeframes established by American Proficiency Institute (API) for Immunology /Immunoematology 2021 Event 2 resulting in unsuccessful proficiency results. Findings: 1. Review of the CMS-155 report on 8/15/2022 at 10:00 AM revealed that the American Proficiency Institute (API) reported scores for 2021 Immunology /Immunoematology 2nd Event was 0%, 2. An interview with TP#1 on 08/31/2022 at 12:51 PM, confirmed the failed scores were due to late submission.