

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409886	(X3) Date Survey Completed 04/28/2020
Name of Provider or Supplier Colstrip Medical Center	Street Address, City, State 6230 Main Street, Colstrip, 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	Based on an off-site proficiency testing desk review conducted on 5/04/2020, deficiencies were cited for Colstrip Medical Center, Colstrip, MT 59323.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. 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, the laboratory failed to achieve satisfactory performance for white blood cell differentials (WBC Diff) for two of three events (2019 event 3, 2020 event 1), resulting in unsuccessful proficiency testing performance. See D2130
D2130	HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive 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, the laboratory failed to achieve a score of 80 percent for WBC Diff in two of three events in 2019 and 2020, resulting in unsuccessful performance. The findings include: 1. During a review on 5/04/20 at 12:06 p.m. of the CMS-153 Unsuccessful Proficiency Testing Report included Colstrip Medical Center with unsuccessful proficiency testing scores for WBC Diff. 2. During a review on 5/04/20 at 12:35 p.m. of the CMS-155 report, the American Proficiency Institute (API) WBC Diff score for event 3 of 2019 was 0%. 3. During a review on 5/04/19 at 12:35 p.m. of the CMS-155 report, the API WBC Diff score for event 1 of 2020 was 0%. 4. On 4/23/19 at 4:36 p.m., the laboratory manager by email sent documents which reported errors for 2019 event 3 and 2020 event 1. Documents indicated the wrong values were submitted to API.