

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0042135	<b>(X3) Date Survey Completed</b>  12/01/2020
<b>Name of Provider or Supplier</b>  Msu Student Health Services	<b>Street Address, City, State</b>  950 W Grant Street, Montana State Univ Bozema, 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>D0000</b>	Based on an off-site proficiency testing desk review conducted on 11/15/2020, deficiencies were cited for MSU University Health Partners in Bozeman, MT.
<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 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 four of four events (2019 Event 3, 2020 Event 1, 2020 Event 2, and 2020 Event 3), resulting in unsuccessful proficiency testing performance. See D2130</p>

**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 four of four events (2019 Event 3, 2020 Event 1, 2020 Event 2, and 2020 Event 3), resulting in unsuccessful proficiency testing performance. The findings include: 1. Review of CMS-2567 with Conditions Out-First Unsuccessful PT Performance dated May 28, 2020 addressed to Cara Maletz. 2. Review of CMS-153 Unsuccessful Proficiency Testing Report on 05/4/20 at 12:06 p.m. and 11/16/20 at 9:10 a.m., which included MSU University Health Partners with unsuccessful proficiency testing scores for WBC Diff. 3. Review of the CMS-155 report on 5/18/20 at 2:35 a.m., revealed the American Association of Bioanalysts (AAB) WBC Diff scores for 2020 Event 3 was 72% and 2020 Event 1 was 60%. 4. Review of the CMS-155 report on 11/16/20 at 10:50 a.m., revealed the American Association of Bioanalysts (AAB) WBC Diff scores for 2020 Event 2 and Event 3 were 60%. 5. The laboratory manager confirmed on 12/01/20 at 10:06 a.m., failed scores due to clerical errors.