

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410751	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Ruby Valley Hospital	Street Address, City, State 321 Madison St, Sheridan, 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 9/30/2020, deficiencies were cited for Ruby Valley Hospital DBA Ruby Valley Medical Ctr in Sheridan, MT.
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, the laboratory failed to achieve satisfactory performance for white blood cell differentials (WBC Diff) for four of seven events (2018 event 2, 2019 event 1 and 3, 2020 event 2), resulting in unsuccessful proficiency testing performance. See D2130</p>

<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>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 seven events (2018 event 2, 2019 event 1 and 3, 2020 event 2), resulting in unsuccessful performance. The findings include: 1. Review of CMS 2567 with Conditions Out-First Unsuccessful PT Performance dated May 14, 2019 addressed to Dr. Shannon on 9/30/2020. 2. Review of CMS-153 Unsuccessful Proficiency Testing Report on 9/30/20 at 10:30 a.m. which included Ruby Valley Hospital DBA Ruby Valley Medical Ctr with unsuccessful proficiency testing scores for WBC Diff. 3. Review of the CMS-155 report on 9/30/20 at 10:30 a.m., revealed the American Proficiency Institute (API) WBC Diff scores for 2019 event 3 was 60% and 2020 event 2 was 4%. 4. Confirmed by email communication with the laboratory manager, the laboratory had four of seven unsuccessful PT scores for WBC Diff. on 9/30/20 at 10:52 a.m.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</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 director failed to provide overall management of the laboratory by failing to ensure the quality assessment (QA) program was adequate and maintained for correct data entry and submission of proficiency testing results for WBC Diff. See D6020.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) scores and interview, the Laboratory Director failed to ensure the quality assessment (QA) program was adequate and maintained for correct data entry and submission of proficiency testing results for Hematology, WBC Diff. The findings include: 1. Review of CMS 2567 with Conditions Out-First Unsuccessful PT Performance dated May 14, 2019 addressed to</p>

Dr. Shannon on 9/30/2020. 2. Review of the CMS-153 Unsuccessful Proficiency Testing Report on 5/14/19 at 7:06 a.m. and 9/30/20 which included Ruby Valley Hospital DBA Ruby Valley Medical Ctr with unsuccessful proficiency testing scores for WBC Diff. 3. Review of the CMS-155 report on 5/14/19 at 7:35 a.m., the American Proficiency Institute (API) WBC Diff score for 2018 event 2 was 20% and 2019 event 1 was 0%. 4. Review of the CMS-155 report on 9/30/20 at 10:30 a.m., the American Proficiency Institute (API) WBC Diff score for 2019 event 3 was 60% and 2020 event 2 was 4%. 5. The laboratory manager confirmed on 9/30/20 at 10:52 a.m., "The instructions state to make sure the Caps Lock is off, which the operator interpreted this to mean lower-case characters were to be used when entering the sample IDs. Sysmex reports that this changes the algorithm used by the instrument in calculating results (and why our numbers were incorrect.)"