

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0411039	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Bitterroot Health Daly	Street Address, City, State 1200 Westwood Dr, Hamilton, 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	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 Total LDH testing for 2 out of 3 events (2020 Event 3 and 2021 Event 1), resulting in unsuccessful proficiency testing performance. See D2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) 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 General Supervisor (GS)#1, the laboratory failed to achieve a score of 80 percent for LDH, Total in 2 of 3 events (2020 Event 3 and 2021 Event 1), resulting in unsuccessful proficiency testing performance. The findings include: 1. Review of CMS-153, Unsuccessful Proficiency Testing Report included Marcus Daly Hospital located in Hamilton, MT with unsuccessful proficiency testing scores for LDH, Total. 2. Review of the CMS-155, Individual Laboratory Report revealed the College of American Pathologists (CAP) LDH, Total scores for 2020 Event 3 and 2021 Event 1 were 0%. 5. Interview with GS#1 on 05/06/2021 at 10:41a.m., confirmed the CAP proficiency test scores for 2020 Event 3 and 2021 Event 1, LDH, Total were unsuccessful due to clerical error with the reagent code. .