

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0411039	(X3) Date Survey Completed 03/14/2022
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with Testing Supervisor (TS) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Chemistry (C-Reactive Protein (CRP)) and Hematology (Reticulocyte Counts) from January 1, 2020 to March 14, 2022. Findings: 1. Review of Test Volume Report revealed 2,671 CRP tests and 77 Reticulocyte Counts were performed for 2021. 2. Review of 2020 and 2021 American Proficiency Institute (API), College of American Pathologists (CAP), and American Association of Bioanalysts (AAB) testing program records lacked documentation of proficiency testing for CRP and Reticulocyte Counts. 3. Interview on March 14, 2022 at 4:30 PM with the TS#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for CRP and Reticulocyte Counts from January 1, 2020 to March 14, 2022.</p>
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</p>

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 record review and interview with Testing Supervisor (TS) #1, the laboratory failed to achieve satisfactory performance scores of 80% for analytes Bilirubin, Direct (Neonatal) and NT pro-BNP (CM) for two out of three events in year 2021, 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 2021 American Proficiency Institute (API) proficiency testing scores and interview with technical supervisor (TS) #1, the laboratory failed to achieve a score of 80% for Chemistry analytes Bilirubin, Direct (Neonatal) and NT pro-BNP (CM) for two of three events. Findings: 1. Review of API proficiency testing scores for Bilirubin, Direct (Neonatal) revealed scores of 50% for 2021 Event 1 and 3. 2. Review of API proficiency testing scores for NT pro-BNP (CM) revealed scores of 60% for 2021 Event 2 and 3. 3. Interview on March 14, 2022 at 4:20 PM with the TS#1, confirmed unsuccessful proficiency scores for Chemistry analytes Bilirubin, Direct (Neonatal) and NT pro-BNP (CM) for two of three events.