

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0411039	(X3) Date Survey Completed 11/27/2023
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	<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 a routine desk audit of the CMS-155 report for proficiency testing (PT) performance, a review of College of American Pathology (CAP) records and interview with the technical supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for urea nitrogen performed on the VITROS 7600 chemistry analyzer for two out of three testing events, resulting in unsuccessful proficiency testing performance. (See D2096)</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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 (PT) scores and interview with technical supervisor (TS) # 1, the laboratory failed to achieve a score of at least 80% for two out of three PT events (2023 CAP C-A and C-C) for urea nitrogen. Findings: 1. A review of the CAP urea nitrogen PT scores revealed that in 2023, CAP C-A scored 20% and CAP C-C scored 0%. 2. An interview with (TS) #1 on November 20, 2023, at 2:36 PM confirmed the failed urea nitrogen PT events were due to calibration and transcription errors.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of College of American Pathology (CAP) proficiency testing (PT) scores and email communication with technical supervisor (TS) # 1, the laboratory failed to provide signed attestation statements, documentation of review, records of corrective actions for 2023 events CAP C-A and C-C and 2023 event CAP C-A results and scores for urea nitrogen. Findings: 1. No records of 2023 event CAP C-A for urea nitrogen were provided for review. 2. No records of signed attestation statements, signed summary of review, and records of corrective actions for 2023 events CAP C-A and C-C were provided for review. 3. An email with (TS) #1 on November 20, 2023, at 2:36 PM confirmed the lack of requested documents for 2023 events CAP C-A and C-C.