

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410840	(X3) Date Survey Completed 06/27/2022
Name of Provider or Supplier Blue Mountain Clinic Family Practice	Street Address, City, State 610 North California Street, Missoula, 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 CMS-155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for ABO /RHO and D (Rho) typing performed on the EldonCard 2521 for three of four events (2021 Event 1, Event 3 and 2022 Event 1), resulting in unsuccessful proficiency testing performance. See D2162.</p>
D2162	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p>

Failure to achieve satisfactory performance for the same analyte 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 testing personnel (TP) # 1, the laboratory failed to achieve a score of 100% for ABO/RHO typing and 100% for D (Rho) typing for three of four events (2021 Event 1, Event 3 and 2022 Event 1). Findings: 1. Review of the CMS-155 report on 2/16/2022 at 7:45 AM and 6/13/2022 at 3:40 PM revealed that the American Proficiency Institute (API) ABO/RHO and D (Rho) typing scores for 2021 Event 1 was 80%, 2021 Event 3 was 60% and 2022 Event 1 was 0%. 2. An interview with TP#1 on 05/17/2022 at 12:51 PM, confirmed the failed scores were due to technical and clerical errors.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

Based on routine desk audit reports of proficiency testing performance, previous deficiency reports and interviews, the laboratory director failed to ensure the quality assessment (QA) program was maintained for verification of correct data entry and submission for proficiency testing results for three of four proficiency testing events for ABO/RHO and D (Rho) typing. See D6018.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of Proficiency Testing (PT) scores from the American Proficiency Institute (API), previous deficiency reports and interview with testing personnel (TP) # 1, the Laboratory Director failed to ensure the quality assessment (QA) program was maintained for verification of correct data entry and submission of proficiency testing results for three of four proficiency testing events. Findings: 1. Review of API Preview Results Form for 2022 Immunology/Immunohematology 1st Event revealed "These Test Results Have Not Been Submitted," resulting in D(Rho) and ABO/RHO typing scores of 0%. 2. The laboratory director failed to prevent a repeat deficiency for unsuccessful proficiency performance for ABO/RHO and D(Rho) typing scores. Cross Refer D2162 3. Review of CMS-2567 signed on 03/14/2022 by the laboratory

director, revealed the allegation of compliance written included a QA plan for proficiency testing entry. 4. An interview with TP#1 on 05/17/2022 at 12:51 PM, confirmed the failed scores were due to technical and clerical errors.