Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410840	09/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Blue Mountain Clinic Family Practice	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records and interview with Testing Personnel (TP) #1, the laboratory director failed to review, sign and date the Proficiency Testing Performance Evaluations for 4 of 12 events in 2019, 1 of 10 in 2020 and one Attestation Statement in 2020. (See D5221) Findings: 1. Review of API's Proficiency Testing Performance Evaluations lacked Laboratory Director's review, corrective action, signature and date for the following proficiencies: a. 2019 Immunology/Immunohematology 2nd Event b. 2019 Chemistry - Miscellaneous-2nd Event c. 2019 Hematology/Coagulation -3rd Event d. 2019 Chemistry Core - 3rd Event e. 2020 Hematology/Coagulation - 1st Event 2. Review of API's Attestation Statement for 2020 Chemistry Core 2nd Event lacked the Laboratory Director's and Testing Personnel's signatures and dates. 3. Interview with TP #1 on September 27, 2021 at 2:30 PM confirmed the laboratory director failed to review, sign and date API's Proficiency Testing Performance Evaluations forms for 4 of 12 events in 2019, 1 of 10 in 2020 and one Attestation Statement in 2020.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of personnel files, Laboratory Manual, and interview with Testing Personnel (TP) #1, the laboratory failed to perform annual competency assessments for the technical consultant (TC) #1 and three of eight testing personnel listed on the CMS-209 Laboratory Personnel Report (TP #6, TP #7, and TP #8) for years 2019 and 2020. Findings include: 1. Review of personnel files for 2019 and 2020 revealed the laboratory failed to perform annual competency for TP #6, TP #7, TP #8 and TC #1. 2. Review of Laboratory Manual, Technical Consultant responsibilities include "H. Evaluating the competency of personnel at least annually based on the following procedures: 1. Direct Observation of routine patient test performance ...6. Assessment of problem solving skills". 3. Review of Wet Mount procedure revealed "Quality Control: There is no quality control available for wet mounts. However, Blue Mountain Clinic is enrolled in proficiency testing to be done at least twice a year. These will be given to all qualified personnel for evaluation along with yearly training per Blue Mountain Clinic Policies". 4. No 2019 and 2020 records were available for review for TP #6, TP #7, TP #8 and TC #1 performing proficiency testing or yearly training. 5. Interview with TP #1 on September 27, 2021 at 1:35 PM, confirmed the laboratory failed to perform annual competency assessment for TP #6, TP #7, TP #8 and TC #1 for years 2019 and 2020.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records and interview with Testing Personnel (TP) #1, the laboratory failed to review unsatisfactory scores and address what corrective actions to take for years, 2019, 2020 and 2021. Findings: 1. Review of 2019, 2020 and 2021 API Performance Summary revealed unsatisfactory scores for the following proficiencies. a. 2019 Immunology/Immunohematology 2nd Event, D(Rho) Type score of 60%. b. 2019 Chemistry - Miscellaneous-2nd Event, 25-OH Vitamin D score of 67%. c. 2019 Hematology/Coagulation -1st Event and 3rd Event, Urine Sediment scores of 50% d. 2019 Chemistry Core - 3rd Event, Total (LIP) and LDL Cholesterol (calc) (LIP) both scored 50% e. 2020 Hematology /Coagulation - 1st Event - Hematology (multiple analytes) scores of 60% f. 2020 Hematology/Coagulation - 2nd Event - pH (Urinalysis) score of 0% g. 2020 Hematology/Coagulation - 3rd Event - Nitrate score of 0% h. 2021 Immunology /Immunohematology - 1st Event, D(Rho) Type score of 80%. 3. API binders lacked documentation of addressing unsatisfactory analytes for years 2019, 2020 and 2021. 4. Review of Laboratory Manual's Job Descriptions for Laboratory Director revealed, "F. Ensure there is an approved corrective action plan that is followed when any PT results are found to be unacceptable or deficient." 5. Review of API Proficiency Testing Performance Evaluations for 2019 lacked Laboratory Director's review and documentation of corrective action for the following proficiencies: a. 2019 Immunology/Immunohematology 2nd Event b. 2019 Chemistry - Miscellaneous-2nd Event c. 2019 Hematology/Coagulation -3rd Event d. 2019 Chemistry Core - 3rd Event e. 2020 Hematology/Coagulation - 1st Event 6. Interview with TP #1 on September 27, 2021 at 2:45 PM confirmed the laboratory failed to address unsatisfactory analytes and document corrective action taken.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory (see D5211), failed to review, sign and date the Proficiency Testing Performance Evaluations for 4 of 12 events in 2019, 1 of 10 in 2020 and one Attestation Statement in 2020 (see D2009) and failed to assure competency assessments for the technical consultant and three of eight testing personnel listed on the CMS-209 Laboratory Personnel Report for years 2019 and 2020 (See D5209).