

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2279585	(X3) Date Survey Completed 04/29/2025
Name of Provider or Supplier Bitterroot Health - Stevi Clinic	Street Address, City, State 3975 Us Highway 93n, Stevensville, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) records and an interview with the general supervisor (GS) #1, the laboratory failed to review and evaluate results obtained from the proficiency testing company for seven out of eight proficiency testing events from January 01, 2024, to April 29, 2025. Findings: 1. A review of proficiency testing (PT) records lacked documentation of API's Performance Review and Corrective Action forms with the Laboratory Director's or Designee's signature and the date PT results were reviewed from January 01, 2024, to April 29, 2025, for the following events: 2024 Microbiology - 1st Event 2024 Microbiology - 3rd Event . 2024 Chemistry - Core - 1st Event 2024 Chemistry - Core - 2nd Event 2024 Chemistry - Core - 3rd Event . 2024 Hematology / Coagulation - 1st Event 2024 Hematology / Coagulation - 3rd Event 2. An interview with GS #1 on April 29, 2025, at 1:20 PM confirmed the laboratory failed to review and evaluate results obtained from the proficiency testing company for seven out of eight proficiency testing events from January 01, 2024, to April 29, 2025.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) records and an interview</p>

with general supervisor (GS) #1, the laboratory failed to evaluate proficiency testing scores for ungraded and unacceptable scores and document the corrective action taken from January 01, 2024, to April 29, 2025. Findings: 1. A review of API 2024 Hematology / Coagulation - 2nd Event records revealed the laboratory failed to evaluate the ungraded PT score for Vaginal Wet Preparation for PT specimen VA-02. 2. A review of API 2024 Hematology / Coagulation - 1st Event records revealed the laboratory failed to evaluate an unacceptable score for mean platelet volume (MPV) for PT specimen XE-04 and document the corrective action taken. 3. An interview with GS #1 on April 29, 2025, at 1:10 PM confirmed the laboratory failed to evaluate ungraded and unacceptable PT scores and document the corrective action taken from January 01, 2024, to April 29, 2025.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the General Supervisor GS (#1), the laboratory failed to establish and follow a quality assurance policy and procedure for the general laboratory systems from April 29, 2023, to April 29, 2025. Findings: 1. No quality assurance policies and procedures to monitor, assess, and correct problems identified in the quality of the laboratory system were available for review. 2. An interview with GS #1 on April 29, 2025, at 3:10 PM confirmed the lack of a quality assurance policy and procedure from April 29, 2023, to April 29, 2025, and that it was currently being written.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation, record review, and an interview with the technical consultant TC (#1), the laboratory failed to monitor the humidity and room temperature as required by the Sysmex XN-430 automated hematology analyzer's manual from April 29, 2023, to April 29, 2025. Findings: 1. On April 29, 2025, at 1:45 PM, observed one out of one XN-430 Automated Hematology Analyzer in the laboratory. 2. A review of the Sysmex XN-L Series Manual revealed that the laboratory failed to ensure that the performance specifications for the operating environment were monitored: ambient temperature between 15 and 35 degrees Celsius (C) and relative humidity between

20% and 85%. 3. No documentation of the laboratory's humidity and ambient temperature monitoring was available for review. 4. An interview with TC #1 on April 29, 2025, at 2:10 PM confirmed laboratory staff were not monitoring the humidity and room temperature as required by the manufacturer's instructions from April 29, 2023, to April 29, 2025.