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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 27D0411039 | (X3) Date Survey Completed 04/09/2024 |
| 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 |
|---------------------------|---|
| 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) and College of American Pathologists (CAP) proficiency testing records and an interview with technical supervisor (TS) #1, the laboratory failed to provide corrective action to prevent recurrence of unsuccessful events for hemocytometer fluid counts (HFC) and lacked a review by the laboratory director for unsuccessful events for Bordetella pertussis, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and hemocytometer fluid counts (HFC) from April 8, 2022, to April 8, 2024. Findings: 1. A review of API proficiency testing records for Bordetella pertussis revealed that 2022 Event 2 scored 0% (not submitted) and Event 3 scored 50%, which lacked a review by the laboratory director from April 8, 2022, to April 8, 2024. 2. A review of API proficiency testing records for SARS-CoV-2 revealed that 2022 Event 2 scored 0% (not submitted) and Event 3 scored 50%, which lacked a review by the laboratory director from April 8, 2022, to April 8, 2024. 3. A review of CAP proficiency testing records revealed results were not submitted for HFC for events 2022 HFC-B and 2023 HFC-A and lacked corrective action to prevent recurrence and a review by the laboratory director from April 8, 2022, to April 8, 2024. 4. An interview with TS #1 on April 8, 2024, at 3:30 PM stated the laboratory director would review and sign the documentation on April 9, 2024, during the survey.</p> |
| D5469 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p> |

Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of chemistry quality control (QC) records, procedures, product inserts, and an interview with the technical supervisor (TS #1), the laboratory failed to establish a procedure to verify or establish new lots of quality control and failed to evaluate and document the acceptability of new lots for nine out of nine chemistry quality control products from April 8, 2022, to April 8, 2024. Findings: 1. The laboratory failed to establish a procedure to verify new lots of assayed QC to include the number, type, and frequency of testing and the criteria for acceptability of new lots of QC per the manufacturer's instructions. a. BioRad Liquichek and Lyphochek products. "Assignment of Values... It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." b. MAS Liquimmune: "Control Ranges... Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges." c. MAS Diabetes "Control Ranges... Good laboratory practice suggest that each laboratory establish its own parameters." 2. The laboratory failed to define a procedure to establish new lots of unassayed QC to include the number, type, and frequency of testing, define the statistical parameters (mean and standard deviation) of each batch and lot number, and define the criteria for acceptability of results. 3. The laboratory failed to provide documentation to verify the new lots of assayed QC results correlate with the established limits and failed to provide documentation of establishing statistical limits for new lots of unassayed QC prior to use at the time of the survey. 4. An interview with TS #1 on April 9, 2024, at 9:00 AM confirmed the laboratory failed to have a procedure to verify new lots of assayed QC and establish new lots of unassayed QC and failed to document and evaluate the acceptability of new lots for nine out of nine chemistry controls from April 8, 2022, to April 8, 2024.