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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 27D0411039 | (X3) Date Survey Completed 04/28/2026 |
| 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 |
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| D0000 | The Montana CLIA Program conducted a recertification survey ending on April 28, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. However, the following standard-level deficiencies were identified during the survey. |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a record review, observation, manufacturer's package inserts, and interviews with Technical Supervisors (TS1 and TS3), the laboratory failed to follow the manufacturer's package insert to ensure 23 out of 25 microbiology American Type Culture Collection (ATCC) quality control material were not used past their expiration date from April 28, 2024, to April 28, 2026. Findings: 1. During an interview on April 28, 2026, at 9:15 AM, TS3 was asked to provide a list of all ATCC quality control organisms with associated lot numbers and expiration dates used for quality checks of media, stains, reagents, and kits. No document was produced. 2. A container holding ATCC quality control organisms was provided on April 28, 2026, at 9:20 AM by TS3 for review, and the following expired products were observed along with the expiration dates listed on the packaging: Culti-Loops Arcanobacterium pyogenes ATCC 19411 expired 7/31/2016 Bacteroides thetaiotaomicron ATCC 29741 expired 2/20/24 Enterococcus faecalis ATCC 51299 expired 3/13/24 and expired 6/3/1016 Escherichia coli ATCC 25922 expired 5/31/2016 and expired 2/28/24 Listeria monocytogenes ATCC BAA 751 expired 4/24/24 and expired 2/29/16 Neisseria gonorrhoeae ATCC 43069 expired 3/19/2024 Pseudomonas aeruginosa ATCC 9721 expired 10/31/2016 Pseudomonas aeruginosa ATCC BAA 1744 expired 4/30/2016</p> |

Staphylococcus aureus ATCC BAA 976 expired 2/15/2024 Staphylococcus saprophyticus ATCC BAA 750 expired 02/13/2024 and expired 2/13/24 Staphylococcus scuri ATCC 29061 expired 3/13/24 Streptococcus agalactiae ATCC 12386 expired 11/30/2016 Streptococcus equi ATCC 43079 expired 6/8/23 Streptococcus thermophilus ATCC 19258 expired 7/25/23 Inocu Swabs S. aureus ATCC BAA 976 expired 4/8/2016 S. enterica ATCC 10708 expired 11/25/2016 KWIK-STIK Enterobacter hormaechei ATCC 700323 expired 4/30/21 Proteus vulgaris ATCC 6380 expired 4/30/24 Quanti-Cult Pseudomonas aeruginosa ATCC 27853 exp 3/19/2024 3. A review of the Culti Loops, Inocu Swabs, KWIK STIK, and Quanti Cult product inserts showed the laboratory did not follow the manufacturer's instructions to discontinue use of products after the listed expiration date. 4. An interview with TS1 on April 28, 2026, at 9:30 AM confirmed that 23 out of 25 ATCC quality controls were expired from April 28, 2024, to April 28, 2026. 5. A review of the test volume sheet revealed 5811 microbiology cultures were performed on patients in the last 12 months, from April 28, 2025, to April 28, 2026.

D5425

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(3)

(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:
 Based on a review of microbiology records and interview with Technical Supervisor (TS1), the laboratory failed to perform a verification study for its Individualized Quality Control Plans (IQCP) to support the quality control (QC) frequency for new lots of three of three medias used for patient blood cultures from April 28, 2024, to April 28, 2026. Findings: 1. A review of microbiology's IQCP failed to include in-house verification data in its Quality Control Plan (QCP) to support the QC frequency for new lots of BacT/ALERT FA Plus Culture Bottle, BacT/ALERT FN Plus Culture Bottle, and BacT/ALERT PF Plus Culture Bottle 2. An interview with the TS1 on April 28, 2026, at 9:40 AM confirmed the laboratory had not conducted a verification study to support its QC frequency for new lots of BacT/ALERT FA Plus, BacT /ALERT FN Plus, and BacT/ALERT PF Plus culture media used for patient blood cultures from April 28, 2024, to April 28, 2026. 3. A review of the test volume sheet revealed 2018 blood cultures were performed on patients in the last 12 months from April 28, 2025, to April 28, 2026.