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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 13D2264847 | (X3) Date Survey Completed 03/13/2025 |
| Name of Provider or Supplier Sterling Urgent Care | Street Address, City, State 2201 Thain Grade, Lewiston, ID | |
| 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 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Proficiency Institute (API) and an interview with the laboratory supervisor on 3/13/2025, the laboratory failed to have testing personnel attest to the integration of PT samples with routine testing of patient samples in 2023 and 2024. The findings include: 1. A review of PT documents for 2023 from API identified that the laboratory failed to have performing testing personnel attest that the PT samples were testing with patient samples for hematology event two (2). 2. A review of PT documents for 2024 from API identified that the laboratory failed to have performing testing personnel attest that the PT samples were testing with patient samples for hematology events two (2) and three (3) and chemistry core event two (2) . 3. An interview with the laboratory supervisor on 3/13/2025 at 1:40 pm confirmed that the laboratory failed to sign attestations in 2023 and 2024. 4. The laboratory reports performing 1,434 tests annually.</p> |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> |

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory supervisor on 3/13/2025, the laboratory failed to follow written procedures to assess testing personnel competency in 2023. The findings include: 1. The CMS 209 identified four (4) testing personnel (TP) performing moderate complexity testing of which two (2) were new since the last inspection on 7/10/2023. 2. A review of laboratory procedures identified that the laboratory established a procedure to assess TP initial training, semiannual and annual competency. 3. A review of training and competency assessment records identified that the laboratory failed to have six month competency assessments for one (6) TP in 2023. 4. An interview with the laboratory supervisor on 3/13/2025 at 1:10 pm confirmed the above findings. 5. The laboratory reports performing 1,434 tests annually.

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 a review of laboratory temperature logs, a direct observation and an interview with the laboratory supervisor on 3/13/2025, the laboratory failed to establish and monitor refrigerator storage temperature for patient samples since the last inspection. The findings include: 1. A review of the laboratory temperature logs identified the sample refrigerator temperature column was marked out since July 2023. 2. A direct observation in the laboratory on 3/13/2025 at 2:55 pm identified a patient specimen refrigerator for which the laboratory failed to monitor temperature. 3. An interview with the laboratory supervisor on 3/13/2025 at 2:55 pm confirmed that the laboratory failed to monitor patient specimen refrigerator storage temperatures. 4. The laboratory reports performing 1,434 tests annually.