| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 06D0518456 | 02/01/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Southeast Colorado Hospital District | 373 E 10th Ave, Springfield, CO | |

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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| **D3001** | FACILITIES<br>CFR(s): 493.1101(a)(1)<br><br>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based upon direct observation, and an interview with General Supervisor #1 (GS #1), revealed that the laboratory had not ensured its biological safety cabinet (BSC) was functioning properly since August 16,2023. The laboratory performs approximately 1,187 microbiology tests annually. Findings include: 1. Based upon direct observation of the laboratory's BSC maintenance record, at approximately 1:30 PM on February 1, 2024, the laboratory had not ensured the BSC was functioning properly since the facility's BSC failed its certification on August 16, 2023. 2. Based on an interview with GS #1, at approximately 1:30 PM on February 1, 2024, confirmed that the laboratory had not ensured the BSC was functioning properly since the facility's BSC failed its certification on August 16, 2023. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation of the laboratory, and an interview with general supervisor #1 (GS #1), the laboratory failed to follow its written policy and procedure |

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| | for labeling aliquoted serum specimens in the blood bank refrigerator. The laboratory conducts approximately 166 immunohematology tests annually. Findings include: 1. Based on a direct observation of the laboratory's blood bank refrigerator at approximately 1:45 PM on February 1, 2024, revealed three unlabeled test tubes containing patient serum aliquots used for blood bank testing. 2. The laboratory's policy and procedure for aliquoting patient specimens states the aliquot must contain two unique patient identifiers. 3. Based on an interview with GS #1, at approximately 1:45 PM on February 1, 2024, confirmed that the laboratory was not following its policy for labeling patient aliquots for testing in the blood bank refrigerator and discarded the unlabeled specimens. |
| **D5507** | BACTERIOLOGY<br>CFR(s): 493.1261(b)(c)<br><br>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on an onsite records review, and an interview with general supervisor #1 (GS #1), the laboratory failed to perform and document quality control reactions of each new shipment of their CHROMagar orientation media as required by the manufacturer since July 2022. The laboratory conducts approximately 397 cultures annually. Findings include: 1. Based on a records review, the laboratory failed to perform and document quality control reactions of each new shipment of their CHROMagar orientation media as required by manufacturer since July 2022. 2. Based on an interview with GS #1, at approximately 1:15 PM on February 1, 2024, confirmed that the laboratory failed to perform and document quality control reactions of each new shipment of their CHROMagar orientation media as required by the manufacturer since July 2022. |