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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0023099 | (X3) Date Survey Completed 07/05/2022 |
| Name of Provider or Supplier Calhoun Liberty Hospital Association, Inc | Street Address, City, State 20370 Ne Burns Ave, Blountstown, FL | |
| 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 |
|---------------------------|---|
| D0000 | A recertification survey was conducted on April 25, 2022 and continued through July 5, 2022 to gather additional documentation. Calhoun Liberty Hospital Clinical Laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. |
| D5781 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager, the laboratory failed to perform and document corrective actions for out of range phlebotomy room temperatures during the months of October, November, and December of 2020 and January, February, March, and April of 2021. Findings include: Based on review of the temperature log for the phlebotomy room, it was revealed that no corrective actions had been performed or documented for temperatures out of range. The laboratory's acceptable range for the phlebotomy room was 20 degrees Celsius to 25 degrees Celsius. The following dates had a temperature out of range: 2020: October 31 - 19.8 degrees Celsius, November 8 - 19.6 degrees Celsius, November 9 - 18.4 degrees Celsius, November 22 - 18.9 degrees Celsius, November 23 - 18.8 degrees Celsius, November 25 - 19.8 degrees Celsius, November 30 - 19.3 degrees Celsius,</p> |

December 2 - 19.9 degrees Celsius 2021: January 10 - 17.8 degrees Celsius, January 15 - 19.8 degrees Celsius, January 17 - 18.8 degrees Celsius, January 18 - 18.6 degrees Celsius, January 25 - 19.8 degrees Celsius, February 17 - 19.1 degrees Celsius, March 7 - 19.7 degrees Celsius, April 2 - 19.5 degrees Celsius. During interview with the laboratory manager at 05:00 p.m. on April 25, 2022, it was confirmed that corrective actions were not performed and documented for temperatures out of range.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview with the laboratory manager, the laboratory failed to perform annual competency assessments on five of twelve testing personnel (A, H, I, K, and L) for 2021. Findings include: Based on review of personnel records, it was revealed that one laboratory personnel (A) and four respiratory personnel (H, I, K, and L) were missing annual competency assessments for 2021. During interview with the laboratory manager on April 25, 2022 at 05:00 p.m., it was confirmed that five of twelve testing personnel were missing annual competencies for 2021.