Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0023099	07/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Calhoun Liberty Hospital Association, Inc	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	An announced CLIA recertification survey was conducted at Calhoun Liberty Hospital Clinical Laboratory on 05/29/2024 - 07/16/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing results and interview, the laboratory failed to evaluate the ungraded proficiency testing scores 1 (1st testing event in 2023) out of 4 testing events in Chemistry, 2 (1st and 2nd testing event in 2023)out of 4 testing events in Hematology, and 3 (2nd and 3rd testing event in 2023 and 1st testing event in 2024) in Microbiology. Findings Included: API test results were reviewed for the 1st, 2nd, and 3rd testing event in 2023 and the 1st testing event in 2024. In the 1st testing event in 2023 in Chemistry the laboratory received an ungraded result for ALT. In the 1st and 2nd testing event in 2023 for Hematology the laboratory received an ungraded result for Lymphocytes. In the 1st testing event in 2024 in Microbiology the laboratory received an ungraded result for Urine Culture Zone, CSF (Cerebral Spinal Fluid) cultures, and CSF susceptibility. In the 2nd testing event in 2023 in Microbiology the laboratory received an ungraded result for Urine culture zone, Blood culture and susceptibility. In the 3rd testing event in 2023 in Microbiology the laboratory received an ungraded result for Urine Culture Zone. Interview on 05/29/2024 at 5:00 PM the Laboratory

	Manager confirmed that there was no corrective action or evaluation of the proficiency testing results that were ungraded.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation, record review, and interview, the laboratory failed to store Siemens Dimension EXL integrated chemistry system Calibrators at the required temperature since received on 03/20/2024. Findings Included: During a tour of the laboratory on 05/29/2024 at 10:00 AM 3 boxes of Siemens Dimension EXL integrated chemistry system Calibrators was observed in a freezer that was at -26.3 degrees Celsius. The calibrator box stated that it was received on 03/20/2024 and the storage requirements were -15 to -25 degrees Celsius. Review of the temperature charts for the freezer revealed that the acceptable range was -20 to -35 degrees Celsius. From March 20, 2024 to May 29, 2024 the temperature was colder than the manufacturer's required -25 degrees Celsius. Interview on 05/29/2024 at 10:15 AM the Lab Manager confirmed that the calibrators were not stored per the manufacturer's instruction and that there was no corrective action.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to have corrective action logs for when quality control (QC) was not in the acceptable range for 2 (2022-2024) out of 2 years reviewed. Findings Included: Review of QC revealed that there was QC that was reran or out of acceptable range with no corrective action documented. Interview on 05/30/2024 at 4:30 PM the Laboratory Manager confirmed that there were no corrective actions.