Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0265635	05/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clinch Memorial Hospital	1050 Valdosta Highway, Homerville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on May 18, 2021. Condition and Standard Citations were found. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the laboratory failed to score 100% for the Immunohematology Blood Bank Compatability Testing for the third event of 2020. Findings: 1 Review of the API PT results for the third event for 2020 for Blood Bank Compability Testing, the laboratory reported sample SER-11 as Not Compatible, the expected result was Compatible. The performance was determined to be unacceptable and the score received was 80%. The laboratory failed to attain an overall testing event score of at least 100 %. 2 Interview with laboratory manager, on May 18, 2021, at approximately 3 pm in the manager's office confirmed that the laboratory failed to attain an overall testing of at least 100 % for Blood Bank Compability Testing for event 3 in 2020.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for Immunohematology, for the year 2020, the laboratory failed to receive a minimum score of 100% for the third event, for Compatibility Testing. The laboratory received an unsuccessful score of 80%. Refer: D2173
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 review of the Competency Assessment Documents from 2020, and staff interview, the blood gas lab failed to evaluate competency using the required six criteria for all blood gas testing personnel and assure that the staff maintained their competency. Findings: 1. Review of the Competency Assessment Documents from 2020, the blood gas lab participated in a skills fair, the documents presented did not evaluate the personnel using the six required criteria to determine competency. 2. Interview with the lab manager, and staff #2 on the Blood Gas 209 CMS form, on May 18, 2021 at approximately 3:30pm in the lab manager's office confirmed that the Competency Assessment was a check sheet from a skills fair at the hospital.