Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0858571	01/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Hematology Care Center Incorporate	501 Riverside Drive, Waycross, 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 recertification survey was performed on January 17, 2023. An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficencies, and no such evidence was provided. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties/subspecialties for 42 CFR.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA)documentation and staff interview, the Laboratory Director(LD) failed to ensure that quality assessment programs were maintained to ensure the quality of laboratory services provided. Findings: 1. Review of the QA documents, available at the time of survey, were last dated December 29, 2020. There were no documents after this date available for review. 2. Staff interview with Testing Personnel #1, #2, and LD, on January 17, 2023, at approximately 2:30 pm, in the front office confirmed the aforementioned statement.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the lack of training documents, and confirmed by staff interview, the Laboratory Director (LD) failed to ensure, prior to testing patients' specimens, that 2 out of 2 testing personnel (TP) had initial training documents for moderate complexity testing. Findings: 1. The laboratory did not provide documentation for 2 out of 2 testing personnel, that were listed on the Laboratory Personnel Report (CMS-209 form), had been trained to perform Moderate Complexity Testing on the Beckman Coulter ACTdiff(ACT diff) Hematology Analyzer. 2. Interview with TP#1, TP#2, and the LD on January 17, 2023 in the front office, at approximately 2:35 pm, confirmed that there were no documented training for 2 out of 2 TP prior to testing patients on the ACT diff.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the lack of a job description documents for 2 out of 2 testing personnel (TP), listed on the Laboratory Personnel Report (CMS209), and confirmed by staff interview, the Laboratory Director (LD) failed to specify, in writing, the responsibilities and duties of each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. The laboratory did not have a policy that identified which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processes, test performance, results reporting, or indicate if director review is required prior to reporting patient test results. Findings: 1. The laboratory could not provide documentation supporting job descriptions for 2 out of 2 TP, listing the responsibilities and duties of each TP. 2. Staff interview with TP#1, TP#2, and the LD, on January 17, 2023, at approximately 2:35 pm in the front office, confirmed the aforementioned statement.