Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0858571	01/22/2019
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 22, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instruction for use of the hematology controls, review of quality control (QC) records and staff interview, the laboratory continued to use hematology controls after they deteriorated and after they exceeded the expiration date. Findings include: 1. Review of the manufacturer's instructions for use of the Beckman Coulter 4C-ES Cell Control revealed the control material is stable for 90 days but only for a maximum of 20 uses within a 35 day period. 2. Review of QC records including logs and Levey Jennings(LJ) charts revealed many days when control values did not fall within the acceptable range on the first attempt and the laboratory ran controls multiple times in an attempt to get two of the three controls within the acceptable range. 3. Review of QC records revealed the laboratory is using the same vial of controls for up to 90 days and is not opening a new vial after 20 uses. 4. Interview with the testing personnel and laboratory director on January 22, 2019 at 1 pm in the area assigned to the surveyor revealed the laboratory is only ordering one vial of 4C -ES Cell Control per lot number and is using the control material past its deterioration date.
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 review of the laboratory's quality assurance (QA) and quality control (QC) records and staff interview, the laboratory failed to document corrective action taken when hematology controls fell outside the acceptable limits. Findings include: 1. Review of the laboratory's 2018 QC records revealed the value of 4C-ES Cell Control fell outside the acceptable range on multiple days. 2. Review of QA records revealed no documentation of corrective action taken when control values were unacceptable. 3. Interview with the testing personnel on January 22, 2019 at 12 pm in the area assigned to the surveyor revealed controls were usually just repeated until at least two of the three levels of control fell within the acceptable range and no corrective action was taken or documented.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017 and 2018 quality control (QC) and quality assurance records (QA) and staff interview, the laboratory director failed to ensure the QA and QC programs were maintained. Finding include: 1. Review of the laboratory's 2017 and 2018 QC & QA records revealed no documentation of review by the laboratory director . 2. Interview with the testing personnel and laboratory director on January 22, 2019 in the work area assigned to the surveyor confirmed the QA and QC activity and/or records are not reviewed by the laboratory director. Also refer to D5417 and D 5783 .
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 laboratory's testing personnel's documentation of competency assessment, lack of records to review as well as interview with the testing personnel and the laboratory director/technical consultant, the technical consultant failed to ensure the competency assessment policy and procedure for testing performed in the speciality of hematology met the 6 required criteria. Findings include: 1. Review of the laboratory competency assessment assessment revealed only a statement signed by the laboratory director/technical consultant stating the testing personnel was evaluated for performance & competency and passed. 2. Review of the statement revealed it does not include the 6 criteria required to assess competency. 3. Review of laboratory records revealed no documentation of the laboratory director/technical consultant's review of QC or QA records which are also required to determine testing personnel competency. 4. Interview with the testing personnel and technical consultant /laboratory director on January 22, 2019 at 1 pm in the work area assigned to the surveyor confirmed competency assessment does not include the 6 required criteria to assess competency.