Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1049996	04/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Candler Medical Oncology Practice	225 Candler Drive, Suite 300, Savannah, 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 April 18, 2019. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 control records and staff interview, the laboratory failed to take corrective action when results of controls for white blood cell (WBC) count fell outside the acceptable range and reported patient results even though control were unacceptable. Finding include: 1. Review of the laboratory's quality control records revealed no Levey Jennings charts available other than for the current lot number in use. 2. Review of the laboratory's cumulative quality control (QC) report from Sysmex for e-check controls, lot # 8128, for May 1, 2018 through July 29, 2018 revealed the laboratory had a positive bias on 5 of 6 control parameters (level 1 & 2 for WBC-C and levels 1, 2, & 3 for WBC-D) and a standard deviation index (SDI) of 3 or greater on 5 of 6 controls. The SDI on the 6th control (level 3 for WBC-C) was 2.7. 3. Review of the raw data report from Sysmex for June 1, 2018 through July 27, 2018 revealed WBC controls were outside the acceptable range on the following: Level 1 for WBC-C 3 of 40 days tested, Level 2 for WBC-C 14 of 40

	days Level 3 for WBC-C 12 of 40 days Level 1 for WBC-D 4 of 40 days Level 2 for WBC-D 13 of 40 days Level 3 for WBC-D 14 of 40 days 4. Review of QC records revealed no documentation of corrective action. 5. Interview with testing personnel # 1 (see CMS 209) on April 15, 2019 at 1 pm in the laboratory confirmed results were outside the acceptable ranges, no corrective action is documented and patient results were reported. 6. Telephone interview with a technical service representative representative from Sysmex on April 17, 2019 at 1:30 pm also confirmed the findings, revealed that control values under WBC-C are from the actual WBC count and values under WBC-D are obtained from the differential portion of the analysis and confirmed that all 6 controls should fall within the acceptable range.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and staff interview, the laboratory director (LD) failed to ensure the laboratory's QC program was maintained. Findings include: Refer to 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 competency assessment records and staff interview, the technical consultant failed to document performing competency assessment on testing personnel. Findings include: 1. Review of 2017 and 2018 competency assessment records for 4 of 4 testing personnel listed on the CMS 209 form revealed the form is only signed by the testing personnel on whom competency assessment is performed and there no documentation showing who performed the competency assessment. 2. Review of the CMS 209 form revealed the technical consultant is the only person qualified to perform competency assessment. 3. Interview with testing personnel # 1 (see CMS 209) and the nurse manager on April 15, 2019 at 12 pm in the office assigned to the surveyor confirmed competency assessment is not performed by the technical consultant and their is no documentation on the form showing who performed the assessment.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

	of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of testing personnel records and staff interview, the laboratory director failed to ensure testing personnel had a minimum of a high school diploma or equivalent. Findings include: 1. Review of testing personnel (TP) records revealed no documentation of a high school diploma or equivalent for 4 of 4 TP. 2. Interview with the nurse manager and testing personnel # 1 (see CMS 209) on April 15, 2019 at 12 pm in the office assigned to the surveyor confirmed documentation of education is not available for TP.