Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0258074	12/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
South Atlanta Hematology Oncology, Pc	253 Upper Riverdale Road, Suite C, Riverdale, 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 December 20, 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:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A review of the procedure manual and interview with the Office Administrator, determined that the laboratory failed to establish a written policy that assess employee competency for the hematology assay performed in the laboratory from March 2018 to December 2019. The findings include: 1. A review of testing personnel records and procedure manual revealed that competency assessments were not performed on any of the testing personnel from March 2018 to December 2019 for the specialty of hematology. 2. The laboratory failed to have a written policy and procedure to assess competency based on the position responsibilities on an initial, semi-annual, and annual bases. 3. An annual competency was not performed for any of the staff from March 2018- 2019. 4. An interview with the Office Administrator in the breakroom on December 20, 2019, at 11:30 AM, confirmed that the laboratory did not have a written policy for assessing employee competency for all tests performed in the laboratory.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Office Administrator, the laboratory failed to follow their own written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment from June 2018 to December 2019. The findings include: 1. The laboratory failed to follow their own QA that assess patient confidentially, specimen integrity and identification, complaint, corrective actions, maintenance, calibration, proficiency test performance, and personnel competency. 2. The laboratory is not performing weekly, monthly, or quarterly QA checks. 3. Testing personnel #1 confirmed on 12/30/19, in the breakroom, at 11:00AM that the laboratory did not follow their own QA policy.
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 quality control records and an interview with testing personnel (TP) #1, the Laboratory Director (LD) failed to ensure that the quality control (QC) and quality assessment (QA) program were maintained for the specialty of hematology. The findings include: 1. A review of daily test logs and quality control (QC) records revealed that the quality controls were not monitor an approved by the LD from June 2018 to December 2019 for the specialty of hematology. 2. The Laboratory Director failed to ensure that the CBC quality controls were acceptable prior to reporting patient results. 3. An interview with the testing personnel # 1 on December 20, 2019 at 11:00 AM in the break room, confirmed that LD was not reviewing QC's for the hematology analyzer prior to reporting patient samples.