Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0882693	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sickle Cell Foundation Of Georgia, Inc	2391 Benjamin E Mays Dr Sw, Atlanta, 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 July 12, 2018. The laboratory was 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: Based on policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow written policies and procedures for performing testing personnel (TP) competencies using the six-procedure competency criteria. 2. An interview with the laboratory manager in a conference room on 7/12/18 at approximately 3 p.m confirmed the laboratory SOP did not contain the six-procedure TP competency policy and procedure.
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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as required. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a quality assurance (QA) policy and procedure for the laboratory. 2. An interview with Staff #1 (CMS 209) in a conference room on 7/12/18 at approximately 3 p.m. confirmed the laboratory SOP did not contain a QA policy and procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to include required documents when applicable to the test procedure. Findings include: 1. SOP document review revealed there was not a policy and procedure for specimen acceptability and rejection. 2. SOP document review revealed there was not a corrective action policy and procedure as required. 3. SOP document review revealed there was not a description of the course of action to take if the hemoglobin electrophoresis test system becomes inoperable. 4. An interview with the lab manager in a conference room on 7/12/18 at approximately 3: 00 p.m. confirmed the aforementioned policies and procedures were not included in the laboratory SOP.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on laboratory document review and staff interview the laboratory failed to monitor and document laboratory temperature as recommended by the manufacturer. Findings include: 1. Laboratory document review revealed the laboratory failed to monitor and document room temperature in 2018 as required for the O-Dianisidine stain used in the Citrate Hemoglobin electrophoresis. 2. An interview with Staff #1 (CMS 209) in a conference room on 7-12-18 at approximately 3 p.m. confirmed the laboratory did not monitor and document laboratory room temperature in 2018.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory test reports and staff interview, the laboratory failed to provide normal values to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. Findings include: 1. Laboratory test report review revealed the test report did not include normal values for the Hemoglobinopathy Fractionation Profile performed in the laboratory. 2. An interview with the lab manager in a conference room on 7/12/18 at approximately 3 p. m. confirmed the laboratory test report did no include normal values for the Hemoglobinopathy Fractionation Profile performed in the laboratory.
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 testing personnel (TP) document review and staff interview, TP failed to meet the educational requirements to perform high-complexity laboratory testing. Findings include: 1. TP document review revealed Staff #2 (CMS 209) failed to meet the necessary requirements to perform high-complexity laboratory testing due to lack of education documentation 2. An interview with Staff#2 (CMS 209) on 7/12/18 in a conference room at approximately 3 p.m. confirmed he did not meet the necessary

	requirements to perform high-complexity testing due to lack of education documentation.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each testing personnel (TP), each supervisor, and each person involved in all phases of laboratory testing as required. Findings include: 1. SOP document review revealed the LD failed to specify in writing the duties and responsibilities of each individual involved in all phases of high-complexity laboratory testing. 2. An interview with Staff #1 (CMS 209) in the conference room on 7/12/18 at approximately 3 p.m. confirmed the SOP did not contain a policy and procedure for duties and responsibilities of each individual involved in all phases of high-complexity laboratory testing.