

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D0882693</p>	<p>(X3) Date Survey Completed</p> <p>03/27/2026</p>
<p>Name of Provider or Supplier</p> <p>Sickle Cell Foundation Of Georgia, Inc</p>	<p>Street Address, City, State</p> <p>2391 Benjamin E Mays Dr Sw, Atlanta, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>On May 05, 2026 an off site follow-up review of the Complaint survey was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations. A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 27, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:</p>
<p>D2000</p>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on Proficiency Testing (PT) documents review and staff interview, the laboratory failed to enroll in a CMS approved PT program for the specialty of Hematology after start of patients testing from May 2024 to March 2026. Findings: 1. Review of Proficiency Testing (PT) records revealed the laboratory failed to enroll in a CMS approved PT testing program for the Mindray BC - 3600 Hematology analyzer for CBC testing that started on May 2024 to March 2026. 2. An interview with the sickle cell sanctuary manager and (TP #4 CMS 209) in the conference review room at approximately 11:30 AM on 03/27/2026 confirmed no enrollment in a CMS approved PT program after start of patient testing from May 2024 to March 2026.</p>

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on documents review and interview with the sickle cell sanctuary manager, the laboratory director failed to ensure that all phases of quality testing (preanalytic, analytic and post analytic) guidelines were followed to identify and fix problems in the laboratory from May 2024 - March 2026 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. (QA) documents review revealed the lab director who is also the technical consultant, had a monthly QA checklist but failed to identify that proficiency testing (PT) records were missing for the Mindray BC - 3600 Hematology analyzer for Complete Blood Count (CBC) from May 2024 to March 2026.. 2. An interview with testing personnel (TP#4 CMS 209) in the conference review room on 03/27/2026 at approximately 12:20 PM, confirmed the lab director failed to ensure proper oversight of the laboratory from May 2024 - March 2026.