| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0882693 | 05/05/2022 |
| **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** | On June 08, 2022 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the laboratory tour, inspection of the flammable cabinet, and an interview with the laboratory Supervisor (TP#2 CMS209), it was determined that the laboratory failed to check its testing reagent supply inventory properly for expiration dates before use in 2021 and 2022. Findings include: 1. Laboratory tour revealed the Methanol Anhydrous expired 05/13/2016 and Odianisidine in Methanol solution used in Hemoglobin (Hgb)Electrophoresis expired in 05/13/2016 . 2. An interview with the laboratory General Supervisor (GS) (TP#2 CMS) at approximately 10:00 am, on 05/05 /2022, during the tour confirmed reagents were expired. |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on Proficiency Testing(PT) document review and staff interview, the laboratory director (LD) failed to ensure all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance to identify any problems that require corrective action. Findings include: 1. College Of American Pathology (CAP) PT document review revealed that the LD failed to ensure all PT reports were reviewed in 2022. Evaluation reports for 2022 Hemoglobinopathy Event #1 was not reviewed and signed by designee or Lab Director. 2. An interview with the laboratory's General Supervisor (GS) (TP#2 CMS 209) on 05/05/2022, at approximately 12:20 pm in the review room confirmed the LD did not evaluate PT results in 1st Event of 2022. |