| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0894890 | 11/22/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Longstreet Clinic Family Medicine Oakwood | 4222 Fairbanks Drive, Oakwood, 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 |
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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on November 22, 2022. 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: |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on Proficiency Testing (PT) records review and staff interview, the laboratory failed to enroll in a CMS approved PT program to verify accuracy of its Chemistry testing with the Abbott I-Stat 1 analyzer in 2021 and 2022. Findings include: 1. Patient records and Proficiency Testing (PT) records review revealed the absence of (PT) records and the lack of evidence of registration with a CMS approved (PT) Agency for the Abbott I-Stat 1 Chemistry analyzer in 2021 and 2022. 2. An interview with the Technical Consultant (TC) (TP #3 CMS 209) on 11/22/2022 at approximately 12:00 PM in the break room confirmed failure of the laboratory to enroll in a CMS approved (PT) program in 2021 and 2022. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c) |

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| | (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>The laboratory failed to maintain satisfactory proficiency testing (PT) performance for automated white blood cell (WBC) differential analytes in 2020, 2021 and 2022 resulting in a second unsuccessful occurrence for WBC differential in two years. (Refer to D 2130). |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on Proficiency Test (PT) document review and staff interview, the laboratory failed to have successful performance in two out of three concecutive testing events in 2020, 2021 and 2022. Findings include: 1. Review of American Proficiency Institute (API) (PT) documents revealed the laboratory failed to have successful performance in Hematology - White Blood Cell Differential Counts for following events: ( Lymphocytes 0% Event 3 of 2020 and 60% Event 1 of 2021), (Basophils 0% Event 2 of 2021 and 20% Event 3 of 2021), (Basophils 20% of Event 3, 2021 and 60% of Event 1, 2022). 2. An interview with the laboratory's, Technical Consultant (TP#3 CMS 209) in the review room at approximately 11:30 AM on 11/22/2022 confirmed the PT unsuccessful findings in 2020, 2021 and 2022. |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<br><br>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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. |

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| | This STANDARD is not met as evidenced by:<br>Based on Proficiency Testing(PT) documents review and staff interview, the Lab Director (LD) failed to ensure that the laboratory was enrolled in a CMS approved (PT) program for all compliance testing analytes as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. (PT) documents review revealed the laboratory director failed ensure the enrollment in a CMS approved (PT) program for compliance testing (using moderate complexity Cartridges) on the Abbott I-Stat 1 Chemistry analyzer as required in 2021 and 2022. 2. An interview with the Technical Consultant (TP#3 CMS209) in the break room on 11/22/2022, at approximately 12:00 PM confirmed the absence of Proficiency Testing (PT) documentation for the aformentioned Chemistry analyzer in 2021 and 2022. |