

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1032047	<b>(X3) Date Survey Completed</b>  10/09/2018
<b>Name of Provider or Supplier</b>  Longstreet Clinic Pc, The	<b>Street Address, City, State</b>  4019 Executive Drive, Oakwood, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 09, 2018. 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:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory's lead technician (PT#1 CMS 209) , the laboratory director failed to attest that PT samples were tested in the same manner as patient specimens by failing to sign attestation forms for Hematology/ coagulation event #1 of 2017. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed the laboratory director failed to sign the attestation documents for the 2017 testing events #1. 2. An interview with the laboratory's lead technician on 10/9/18 at approximately 12:33 PM in the patient review room, confirmed the attestation was not signed.</p>
<b>D6049</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Quality Assurance(QA) records and an interview with the laboratory's lead technician, the Technical Consultant (TC) failed to review and sign Monthly Quality Assurance report records for July and September of 2018. Findings include: 1. Review of maintenance and Quality Assurance reports revealed QA logs were not reviewed and signed for the months of July and September of 2018 by (TC). 2. An interview with the laboratory's lead technician (TP#1 CMS 209) on 10/09/2018 at approximately 12:40 pm in the patient review room confirmed the QA reports were not reviewed and signed by the (TC).

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on Proficiency Test (PT) review and an interview with the laboratory's lead tech (TP # 1 CMS 209), the laboratory director (LD) failed to ensure that corrective action was performed for an unsatisfactory PT result. 1. American Proficiency Institute (API) PT document review revealed the LD failed to ensure corrective action was taken and documented for 2017 (1st Event RBC count result of 80%). 2. An interview with the laboratory's lead tech (TP# 1 CMS 209) on 10/09/2018 in the patient review room at approximately 12:35 pm confirmed no corrective action was taken and documented for the unsatisfactory 2017 ( 1st Event RBC count results of 80%).