Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2131391	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier The Longstreet Clinic, P C , At Highpoint	**Street Address, City, State** 1270 Friendship Road, Braselton, 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	An offsite revisit survey was conducted on August 16, 2018, for all previous deficiencies cited on 6/19/2018. All deficiencies have been corrected. The facility is in compliance with with all regulations surveyed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. 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 a policy and procedure for test record retention. Findings include: 1. SOP review revealed the laboratory failed to establish a policy and procedure for test record retention. 2. An interview with Staff #2 (CMS 209) in the breakroom on 6/19/18 at approximately 2:30 p.m. confirmed the SOP did not contain a policy and procedure for test record retention.
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 SOP failed to include required preanalytic, analytic, and postanalytic policies and procedures when applicable to the test procedure. Findings include: 1. SOP review revealed the SOP did not contain the following required policies and procedures applicable to the test procedure: laboratory specimen storage, criteria for specimen acceptability and rejection, quality control (QC) policies and procedures for hematology and chemistry, a QC policy and procedure for bacteriology media, and a QC policy and procedure for the bacteriologyTaxo disc. 2. An interview with Staff #2 (CMS 209) in the breakroom on 6/19/18 at approximately 2:30 p.m. confirmed the aforementioned items were not included in the laboratory SOP.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation documents and staff interview, the laboratory failed to demonstrate the accuracy, precision, and reportable range of the hematology test system as required before reporting patient test results. Findings include: 1. Review of the Abbott Cell-Dyn Emerald hematology analyzer validation documents revealed there was no record of correlation studies performed in 2017 before reporting patient test results. 2. An interview with Staff #2 (CMS 209) on 6/19/18 in the breakroom at approximately 2:30 p.m. confirmed correlation studies were not performed in 2017 for the Abbott Cell-Dyn Emerald hematology analyzer prior to reporting patient test results.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)

	Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory test reports and staff interview, the laboratory failed to include all required facility information on the test report. Findings include: 1. Laboratory test report review revealed the test report did not contain the correct address for the testing facility. 2. An interview with the laboratory supervisor at her desk on 6/19/18 at approximately 2:00 pm. confirmed the laboratory test report did not contain the correct testing facility address.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory testing personnel (TP) competencies and staff interview, the technical consultant (TC) failed to perform competencies for TP responsible for moderate complexity testing at least semiannually during the first the TP tests patient specimens as required. Findings include: 1. TP competency review revealed the TC failed to perform six-month competencies in 2018 for Staff #2 (CMS 209) and Staff #3 (CMS 209). 2. An interview with Staff #2 (CMS 209) on 6/19/18 in the breakroom at approximately 2:30 p.m. confirmed the TC did not perform six-month competencies for the aforementioned TPs in 2018.