

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0913739	(X3) Date Survey Completed 01/09/2018
Name of Provider or Supplier Longstreet Clinic Pediatrics Dept	Street Address, City, State 155 Professional Drive, Baldwin, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 9, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 proficiency testing (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD failed to sign the following attestation statements: 2016 --3rd event Chemistry; 2017 -- 1st, 2nd, and 3rd events Microbiology and Chemistry; 2017 -- 3rd event Hematology/Coagulation. 2. An interview with Staff #2 (CMS 209) on 1/9 /17 in an office area at approximately 1:30 p.m. confirmed the LD did not sign the aforementioned PT attestation statements.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel</p>

have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure all TP receive the appropriate training and demonstrate competency in the type and complexity of the laboratory services offered. Findings include: 1. TP document review revealed the LD/TC failed to ensure an initial training competency was performed on Staff #4 (CMS 209) in 2016. 2. An interview with Staff #2 (CMS 209) on 1/9/17 in a medical office area at approximately 1:30 p.m. confirmed the LD/TC failed to ensure an initial training competency was performed on Staff #4 (CMS 209) in 2016.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory director (LD) failed to ensure policies and procedures were established for monitoring testing personnel (TP) to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results. Findings include: 1. SOP review revealed the LD failed to ensure policies and procedures were established to evaluate the competency of TP for initial training, 6-month competency, and annually thereafter. 2. An interview with Staff #2 (CMS 209) in an office area at approximately 1:30 p.m. on 1/9/18 confirmed there was not a competency policy in the SOP for initial training, 6-month competency, or annually thereafter.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory maintenance logs, quality control (QC) logs, and quality assurance (QA) reports, the technical consultant (TC)/laboratory director (LD)

failed to perform a review of the aforementioned documents. Findings include 1. Hematology Emerald Cell-Dyn 1800 QC log review, Emerald Cell-Dyn 1800 maintenance log review, and laboratory QA report review revealed the TC/LD failed to review the aforementioned documents for 2016 and 2017. 2. An interview with Staff #2 on 1/9/17 in a medical office area at approximately 1:30 p.m. confirmed the TC/LD failed to review of the aforementioned documents for 2016 and 2017.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical consultant (TC)/laboratory director (LD) failed to perform annual TP competencies as required. Findings include: 1. TP document review revealed there were no 2017 annual competency documents available for 4 of the 4 TP. 2. An interview with Staff #2 (CMS 209) in a medical office area on 1/9/17 at approximately 1:30 p.m. confirmed there were no annual competency documents available for 4 of the 4 TP.