

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0676736	(X3) Date Survey Completed 09/05/2019
Name of Provider or Supplier Gwinnett Pediatrics	Street Address, City, State 3790 Pleasant Hill Road, Suite 230, Duluth, 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 September 5, 2019. 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:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the lack of an attestation statement for the third hematology event of 2018. 2. An interview in a medical office on 9/5/2019 with the administrative nurse manager at approximately 2:00 p.m. confirmed the lack of an attestation statement for the aforementioned API PT event.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on laboratory maintenance log review and staff interview, the laboratory failed to monitor and document laboratory temperature and humidity as required. Findings include: 1. Laboratory temperature and humidity log review for 2019 revealed room temperature (RT), refrigerator temperature (RFT), and humidity were not monitored and documented for the following days: March -- three of twenty one days (RT and RFT); four of 21 days for humidity; February -- three of twenty days for RT, RFT, and humidity. 2. An interview in a medical office on 9/5/2019 at approximately 2:30 p. m. with the administrative nurse manager confirmed the aforementioned lack of RT, RFT, and humidity monitoring and documentation in 2019.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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 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 (LD) failed to ensure all TP receive the appropriate training and have demonstrated they can perform all testing for the type and complexity of the services offered as required. Findings include: 1. TP competency document review revealed initial competencies were not performed onsite for the following TP in 2019 -- Staff #9 (CMS 209) and Staff #10 (CMS 209). 2. An interview with the administrative nurse manager in a medical office on 9/5/2019 at approximately 11:00 a.m. confirmed the aforementioned TP did not have a 2019 initial competency performed. .

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 testing personnel (TP) document review and staff interview, the technical

consultant/laboratory director (TC/LD) failed to perform onsite semi-annual competencies on TP as required. Findings include: 1. TP competency document review revealed the lack of a six-month onsite competency documents for Staff # 8 (CMS 209) in 2018. 2. An interview with the administrative nurse manager in a medical office on 9/5/2019 at approximately 11:30 a.m. confirmed there was no onsite six-month competency performed in 2018 for Staff #8 (CMS 209).

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/laboratory director (TC/LD) did not perform an onsite annual competency on TP as required. Findings include: 1. TP competency document review revealed an onsite annual competency was not performed for Staff #8 (CMS 209) in 2018. 2. An interview on 9/5/2019 in a medical office with the administrative nurse manager at approximately 11: 45 a.m.confirmed the aforementioned TP did not have an onsite annual competency performed in 2018.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory failed to employ qualified TP to perform laboratory testing due to lack of education documentation. Findings include: 1. TP document review revealed Staff #3 (CMS 209) is unqualified to perform laboratory testing due to lack of education documentation. 2. An interview with the administrative nurse manager on 9/5/2019 in a medical office at approximately 12:00 p.m. confirmed the lack of education documentation for the aforementioned TP.