

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0954325	<b>(X3) Date Survey Completed</b>  06/25/2019
<b>Name of Provider or Supplier</b>  Conyers Pediatrics Pc	<b>Street Address, City, State</b>  7138c Highway 212, Covington, 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 June 25, 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:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory maintenance document review and staff interview, the laboratory failed to monitor and document temperature and humidity as required. Findings include: 1. Temperature and humidity log review revealed laboratory room temperature and humidity were not monitored nor recorded from January 1, 2019 through March 10, 2019. 2. Temperature and humidity log review revealed no acceptable ranges for room temperature or humidity for the following dates: 2017 -- October through December; 2018 -- July through September 3. An interview with Staff #2 (CMS 209) in the conference room on 6/25/2019 at approximately 2:30 p.m. confirmed temperature and humidity were not monitored nor documented for the aforementioned dates. 4. An interview with Staff #2 (CMS 209) at the nurses station on 6/25/1019 at approximately 2:45 p.m. confirmed missing room temperature and humidity ranges on log sheets for the aforementioned dates.</p>

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to delegate the responsibility TP performance evaluation to qualified staff as required. Findings include: 1. TP competency document review revealed unqualified TP performed the 2018 annual competencies for the following TP: (CMS 209 -- Staff #3 through Staff #8) 2. An interview with Staff #2 (CMS 209) in a conference room on 6/25/2019 at approximately 3:00 p.m. confirmed the aforementioned TP competencies were performed by unqualified TP.

**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) failed to performed an annual competency on TP as required. Findings include: 1. TP competency document review revealed the TC /LD failed to perform a 2018 annual competency on Staff #2 (CMS 209). 2. An interview with Staff #2 (CMS 209) in a conference room on 6/25/2019 at approximately 3:00 p.m. confirmed the aforementioned lack of annual competency performance.