

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0676735	(X3) Date Survey Completed 05/01/2019
Name of Provider or Supplier Gwinnett Pediatrics & Adolescent Medicine	Street Address, City, State 595 Hurricane Shoals Rd, Nw, Lawrenceville, 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 May 1, 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:
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on hematology quality control (QC) document review and staff interview, the laboratory failed to perform corrective action to ensure the reporting of accurate and reliable patient test results as required. Findings include: 1. Emerald Cell-Dyn QC document review revealed QC results were out of acceptable range for the following dates in 2019 with no corrective action: February -- 2 out of 20 days; March -- 3 out of 21 days. 2. An interview with Staff #6 (CMS 209) in a medical office at approximately 2 p.m. confirmed the aforementioned lack of corrective action.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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</p>

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) competency document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to delegate TC responsibilities to qualified personnel as required. Findings include: 1. TP competency document review revealed the LD/TC delegated (initial, six month, annual) competency-performance responsibilities to unqualified TP for 2017, 2018, and 2019 thus far, due to lack of educational qualifications. 2. An interview with Staff #6 (CMS 209) in a medical office on 5/1/2019 at approximately 1:45 p.m. confirmed the aforementioned TP competencies were performed by unqualified TP due to lack of educational qualifications.