

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0938974	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier Cumming Pediatric Group Pc	Street Address, City, State 1800 Northside Forsyth Drive Suite 460, Cumming, 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 July 10, 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) documents and staff interview, the laboratory failed to examine or test the PT samples with the regular patient workload by personnel who routinely perform the testing in the laboratory. Findings include: 1. Review of American Academy of Family Physicians (AAFP) PT documents revealed Staff #2 (CMS 209) performed all Hematology PT laboratory testing for the following events: 2016 - Event 3; 2017 - Events 1, 2, and 3; and 2018 - Event 1. 2. An interview with Staff #2 (CMS 209) in the laboratory on 7/10/18 at approximately 1:00 p.m. confirmed the same testing personnel performed all PT laboratory testing for the aforementioned events.</p>
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>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) document review and staff interview, the laboratory director (LD) and the testing personnel (TP) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the LD and TP failed to sign the attestation statements for the following Hematology PT events: 2016 - third event; 2017 - first, second, and third events; 2018 - first event. 2. On the aforementioned PT attestation documents, the LD and TP names were printed by Staff #2 (CMS 209). 3. An interview with Staff #2 (CMS 209) in the laboratory on 7/10/18 at approximately 1:00 p.m. confirmed Staff #2 (CMS 209) printed her name and the LD's name on the aforementioned PT attestation statements.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) documents and staff interview, the laboratory director (LD) failed to ensure all PT reports received were reviewed as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the LD did not review the following Hematology PT event results: 2016 - third event; 2017 - first, second, and third events; 2018 - first event. 2. An interview with Staff #2 (CMS 209) on 7/10/18 in the laboratory at approximately 1:00 p.m. confirmed the LD did not review the aforementioned PT event results.