Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2054167	(X3) Date Survey Completed 12/08/2020
Name of Provider or Supplier Gwinnett Pediatrics & Adolescent Medicine	**Street Address, City, State** 4700 Nelson Brogdon Blvd, Ste 180, Sugar Hill, 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 December 8, 2020. 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to ensure the PT samples were tested by testing personnel (TP) who routinely perform laboratory testing as required. Findings include: 1. Review of American Proficiency Institute (API) document review revealed Staff #3 (CMS 209) and Staff #6 (CMS 209) failed to participate in PT for the following Hematology events: 2019 - Event Two and Event Three; 2020 - Events One, Two, and Three. 2. An interview with Staff #3 (CMS 209) in the breakroom on 12/8/2020 at approximately 1:00 p.m. confirmed Staff #3 (CMS 209) and Staff #6 (CMS 209) did not participate in the aforementioned PT events.
D6071	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(2) Each individual performing moderate complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples.

	This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain PT records as required. Findings include: 1. Review of American Proficiency Institute (API) document review revealed the lack of PT reports available at the time of survey for the following Hematology events: 2019 - Event One; 2020 - Event Two and Event Three. 2. An interview with Staff #3 (CMS 209) in the breakroom on 12/8/2020 at approximately 1:00 p.m. confirmed the lack of PT reports available at the time of survey for the aforementioned PT events.