Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0938974	10/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cumming Pediatric Group Pc	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 October 18, 2024. 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on manufacturer's guideline review and staff interviews, the laboratory director failed to enroll in a CMS approved Proficiency Testing (PT) program for Respiratory Syncytial Virus (RSV) testing on patients greater(>) than seven(7) years old from November 2022 through day of survey 10/18/2024. Findings: 1. Manufacturer's guideline review revealed the laboratory failed to follow its own procedure by not enrolling in a CMS accredited PT testing program for (RSV) testing on patients greater (>) than seven(7)years old that upgrades it to moderate complexity from November 2022 to 10/18/2024. 2. An interview with the lab manager, in the break room, at approximately 1:00 PM, on 10/18/2024, confirmed the lack of enrollment in a CMS approved PT program from November 2022 to 10/18/2024.

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patients final reports and the QC screen results of the Picollo Abaxis Chemistry analyzer, the laboratory failed to have normal QC ranges displayed on the analyzer print out on the day of survey 10/18/24. Findings, 2. A review of the current patients final reports and QC (Quality Control) printouts on the Picollo Abaxis Chemistry analyzer, with TP#3 CMS 209, revealed no normal ranges on both printouts on the day of survey 10/18/2024. 3. An inteview with the lab manager, in the break room , on 10/18/2024, at approximately 12:30 PM, confirmed the above findings.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on documents review and interview with the lab manager, the Lab Director (LD) failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from November 2022 to 10/18/2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Monthly QA document review revealed the Lab director, who is also the Technical Consultant (TC), did not enroll in a CMS accredited Proficiency Testing program for RSV testing on patients greater than seven years old from November 2022 to 10/18 /2024. 2. An interview with the laboratory manager in the break room on 10/18/2024 at approximately 1:35 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory testing from November 2022 to 10/18/2024.