Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1061157	12/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Brentwood Pediatric & Adolescent Associates Pc	1464 Fifth Avenue, Bay Shore, NY	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of laboratory's American Academy of Family Physicians Proficiency Testing (AAFP PT) summary report of second event of year 2022, the laboratory failed to document evaluation and verification activities Findings 1. AAFP PT Second event: WBC 80%, Lymph 80%, Granulocyte 80%, RBC 60%, HGB 60%, HCT 60%, PLT 80%. 2. Confirmed in an interview with laboratory director on 12/12 /2023 about 12:30pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on the lack of humidity log, the laboratory failed to monitor humidity since implementation August 2019 through survey date as required by Horiba Micros ABX 60. Finding: 1. Horiba Micros 60: Humidity 20-80% 2. Confirmed on an interview with practice manager on 12/12/2022 about 12pm

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Horiba Micros ABX 60. Findings: 1. The new QC lot to lot validation documentations of hematology analyzer were not available upon request during the survey since the hematology analyzer implementation date to survey date. 2. The laboratory director confirmed during interview on 12/12/2022 about 12pm.