Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1061157	01/23/2025
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 review of laboratory testing logs, Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records, as well as interview with the Laboratory Director (LD), the laboratory failed to test PT samples by testing personnel (TP) who routinely perform patient testing. FINDINGS: 1. Laboratory testing logs documented ten TP who routinely perform patient testing yet WSLH PT records from 2023 through the survey date did not document rotation of PT among the respective ten TP. 2. The LD confirmed the findings on January 23, 2025, at approximately 11:30 A.M.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on review of WSLH PT records as well as interview with the LD, the laboratory failed to retain documented attestation to routine integration of the samples into the patient workload using the laboratory's routine methods. FINDINGS: 1. There

	was no documentation of WSLH PT signed attestation for calendar year 2023 through survey date. 2. The LD confirmed the findings on January 23, 2025, at approximately 11:30 A.M.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the WSLH PT summary reports as well as interview with the LD, the LD failed to document review and date of review of the results obtained on proficiency testing performed. FINDINGS: 1. There was no documentation of WSLH PT summary report LD review and date of review for calendar year 2023 through survey date. 2. The LD confirmed the findings on January 23, 2025, at approximately 11:30 A.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 lack of laboratory humidity records, review of standard operating procedures (SOPs), patient specimen analyzer manufacturer's specifications, as well as interview with the LD, the laboratory failed to monitor and document humidity in the area where on-site laboratory testing was performed. FINDINGS: 1. The patient specimen Horiba ABX Micros ABX 60 analyzer manufacturer's specifications indicated acceptable humidity range of 20% - 80%. 2. There was no monitoring and documentation of humidity in the area where patient testing was performed from January 2024 through survey date. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The LD confirmed the findings on January 23, 2025, at approximately 11:00 A.M. This is a repeat deficiency from on-site survey performed December 12, 2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to

	verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of analyzer calibration records, SOPs, as well as interview with the LD, the laboratory failed to perform and document patient specimen processing analyzer calibration verification. FINDINGS: 1. Horiba ABX Micros 60 analyzer calibration documentation was performed once in 2024. 2. This is contrary to instructions included in the current, approved SOPs which require twice per year analyzer calibration performance. 3. The LD confirmed the findings on January 23, 2025, at approximately 11:00 A.M.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of WSLH PT summary reports, current, approved SOPs, patient specimen analyzer manufacturer's specifications, lack of humidity records, as well as interview with the LD, the LD failed to provide overall management and direction of the laboratory services. Refer to D2007, D2009, D50211, D5413, and D5439.