

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1061157	(X3) Date Survey Completed 10/21/2019
Name of Provider or Supplier Brentwood Pediatric & Adolescent Associates Pc	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records and confirmed in an interview with the laboratory director, the laboratory failed to enroll in an approved PT program for hematology testing when patient testing was initiated in August 2019. FINDINGS: The laboratory director confirmed on October 21, 2019 at approximately 11:00 AM that the laboratory initiated hematology patient testing in August 2019 but did not enroll in a PT program.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p>

	<p>This STANDARD is not met as evidenced by: Based on lack of PT records, the laboratory director failed to ensure that the laboratory is enrolled in an approved PT program for hematology for the second and the third events 2019. FINDINGS: The the laboratory director, confirmed on 10/21 /2019 at 11:30 AM that the laboratory initiated hematology testing in August 2019 but did not enroll in PT for this specialty for the second and the third events in 2019. Refer to D2000.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on a surveyor review of personnel records and confirmed in an interview with the laboratory director, the laboratory director failed to ensure that one of eight testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing. Refer to D6065</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of personnel records and confirmed in an interview with the laboratory director at the time of the survey, the laboratory director failed to ensure that one of eight testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.</p>