

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0879365	(X3) Date Survey Completed 08/24/2020
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 19615 S State Rd 7 #32, Boca Raton, FL	
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 recertification survey conducted on 08/24/2020 found that the Pediatric Associates - Boca Raton clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition level deficiency was cited: - D6063-Testing Personnel
D6063	<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 record review and staff interview, the laboratory failed to remove a testing personnel that did not meet the requirements since 12/16/2019 to 8/6/2020. (See D6065)</p>
D6065	<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</p>

high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to remove a testing personnel that did not meet credential requirements after the evaluation was completed for the period since 12/16/2019 to 8/6/2020. Findings include: - Review of CMS form 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 8/24/2020 revealed one testing person (TP A). -Review of attestation proficiency testing records signed on 6/22/2020 and 7/9/2020 revealed that testing person (TP B) was not listed on CMS 209. -Review of foreign credential evaluation report for TP B, released on 12/16/2019 revealed that she did not meet the requirements because her records did not fulfill the High School level of education. - Review of laboratory records revealed that TP B, performed laboratory tests until 8/6/2020. During an interview on 8/24/2020 at 2:30 pm with laboratory manager, she confirmed that the laboratory failed to remove a TP who was not qualified during the period of 12/16/2019 to 8/6/2020.