

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2138812	(X3) Date Survey Completed 10/30/2019
Name of Provider or Supplier Pediatric Associates Hialeah	Street Address, City, State 1193 W 49th St, Hialeah, 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, 10/30/2019 found that Pediatric Associates Hialeah clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 Laboratory Personnel form, review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Laboratory Manager (LM), the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Bacteriology, Chemistry and Hematology specialties for 2 out of 2 years (2018 - 2019) reviewed. Findings include: 1-Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 10/30/2019 had 3 testing personnel listed (TP A, TP B and TP C). 2-Review of employee folders revealed the following hiring dates -TP A started on 6/3/2019 -TP B started on 10/30/2017 - TP C started on 4/17/2018 3-Review of API PT records revealed that: -For TP B, there was no documentation of PT testing in Bacteriology Specialty for 2018 and 2019, Chemistry Specialty during 2019 and Hematology on 2018 and 2019. -For TP C, there was no documentation of PT testing during 2018 and 2019 for Bacteriology, Chemistry and Hematology specialty. During an interview on 10/30/2019 at 12:00 PM, LM confirmed that TP B and TP C missed to participate in PT during the years of above-reference.</p>