

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2090334	(X3) Date Survey Completed 10/25/2018
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 3950 N 46th Ave, Hollywood, 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
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 API (American Proficiency Institute) proficiency testing record review for two-year period (2016 to 2018), and interview with laboratory manager, the laboratory failed to rotate proficiency testing (PT) events to include all testing personnel who routinely performed patient testing, for 6 out of 6 events reviewed for bacteriology and routine chemistry. The findings include: On October 25, 2018 at 1:30pm surveyor reviewed API proficiency testing records from year 2016 to 2018. Record review revealed that: 1) Testing person #2 did not perform routine chemistry or bacteriology proficiency testing for 6 out of 6 events. During an interview on October 25, 2018, at 2:00pm, the laboratory manager confirmed that laboratory did not rotate testing person #2 for 6 out of 6 proficiency-testing events from 2016 to 2018 for bacteriology and routine chemistry.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on two year (2016 to 2018) API proficiency testing record review and</p>

interview with laboratory manager, - there was no testing person signature on attestation statement for 2nd event, 2018. -Attestation statements- Sample set(s) tested was left blank. The findings include: API Proficiency testing record review on 10/25/18 at 1:30pm for two-year review period (10/2016 to 10/25/2018) showed that 1- Attestation statement 2018 chemistry-core - 2nd event- not signed by person performing the test. 2- Attestation statements for 2017-hematology/ coagulation 1st and 2nd events, 2018 chemistry-core - 2nd event, and 2018 microbiology - 2nd event did not specify the API proficiency test sample set(s) tested. During an interview on 10/25/18 at 2:00 PM, laboratory manager confirmed the findings 1 to 3 for the API proficiency testing attestation statements.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on record review of competency performance record review for two-year period (2016 to 10/25/2018), technical consultant failed to document moderate complexity annual competency for 1 out of 2 testing personnel. The findings include: Laboratory personnel records reviewed on 10/25/18 at 1:30pm for two-year review period (10/2016 - 10/25/2018) for hematology (RBC, WBC differential, platelets, hemoglobin, hematocrit,), routine chemistry (neo bilirubin) and bacteriology (strep A culture) did not show written documentation of moderate complexity testing personnel annual performance evaluation for testing person #2. Performance evaluation records for testing person #2 showed the initial competency evaluation on 10/3/16, semiannual evaluation on 4/26/17 and next evaluation over a year after that on 9/26/18., thus missing annual performance review.