

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0693834	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 101 N Country Club Rd #116, Lake Mary, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to obtain the signatures on the attestation form of all testing personnel who analyzed the proficiency testing for bacteriology identification for 5 out of 5 testing events reviewed from December 2016 through December 2018. Findings: Review of College of American Pathologist (CAP) PT for the 1st, 2nd, and 3rd events in 2017, and the 1st and 2nd events in 2018 showed only one signature for the testing personnel on the attestation form. The signature on the attestation was the signature for Testing Personnel I, who was not qualified to report the final test results. During an interview on 12/12/18 at 3:25 AM, Lead Medical Assistant stated that Testing Personnel I only performs the set up of the bacterial agar plates and does not report the final test results. Lead Medical Assistant also stated she did not know that the personnel reporting the final test results needed to sign the attestation form.</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p>

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to receive a score of at least 80% in the proficiency testing (PT) for bacterial identification for the 1st testing event in 2018. Findings: Review of College of American Pathologist (CAP) PT results showed that the laboratory received a score of 38% for bacterial identification for the 1st testing event in 2018. During an interview on 12/12/18 at 2:45 PM, Lead Medical Assistant acknowledged that they had not received at least 80% for bacterial identification for the 1st testing event in 2018.