

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1007296	(X3) Date Survey Completed 09/26/2019
Name of Provider or Supplier Grifton Pediatrics	Street Address, City, State 416 Mccrae Street, Grifton, NC	
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 review of 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) 9/26/19, the laboratory failed to maintain signed attestation statements to document that PT sample were tested in the same manner as patient specimens. Findings: Review of 2018 and 2019 APT PT records revealed the following attestation statements were not signed by the laboratory director (LD) and/or the testing personnel (TP) who participated in the event. 2019 API PT Hematology/Coagulation (H/C) 2nd Event - attestation not signed by LD and TP. 2019 API PT H/C 1st Event - attestation not signed by LD and TP. 2018 API PT H/C 3rd Event - attestation not signed by TP. 2018 API PT H/C 2nd Event - attestation not signed by TP. Interview with TP #2 at approximately 12:00 p. m. confirmed the attestation were not signed, she stated she was unsure now that API submission was on-line and that she had typed the names in on the API website and thought that was all that would be required.</p>