

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0880781	<b>(X3) Date Survey Completed</b>  03/11/2020
<b>Name of Provider or Supplier</b>  Donald B Morris Md Pa	<b>Street Address, City, State</b>  1111 7th Ave N Ste 101, Saint Petersburg, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Donald B Morris MD PA on 03/11/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 American Proficiency Institute (API) proficiency record review, record review of the policy and procedure manual, and interview with the Laboratory Director, the laboratory failed to have documentation of signed attestations for the Hematology/Coagulation PPM/Urine Sediment proficiency testing for two of two years reviewed (2018-2019). Findings included: Review of the policy and procedure manual revealed "Proficiency Test Procedure" which stated "records will be retained for a period of 2 years". Review of API Hematology/ Coagulation PPM/Urine Sediment proficiency records for 2018-2019 (1st, 2nd and 3rd Events for 2018 and 2019) revealed the assigned attestation statement page was missing from the proficiency testing records. Interview on 03/11/20 at 1:05 P.M., the Laboratory</p>

Director confirmed the attestation statements were missing for 2018 and 2019. He stated he probably threw them away when cleaning out the proficiency testing binder.