

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283602	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier Goodman Neil F Md Pa	Street Address, City, State 4675 Ponce De Leon Blvd Ste 204, Miami, 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 was conducted on November 19, 2019. Goodman Neil MD PA clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run proficiency testing (PT) samples the same number of times, as it routinely tests patient samples for 2018 (2nd event) and 2019 (1st and 2nd event) for the specialty of Hematology. Findings: Review of the laboratory's proficiency testing records with American Association of Bioanalysts (AAB) for 2018 2nd event and 2019 1st and 2nd events showed that the laboratory performed the manual semen counts on the PT samples more than once. Handwritten results of the semen counts showed more than one testing personnel record results for each sample. Review of the laboratory's Proficiency Testing procedure states "The person performing the testing must attest the samples have been tested as the patient's samples." During an interview on 11/19/19 at 10:30 AM, Testing Personnel B stated that all testing personnel performed the semen counts for the proficiency testing and that each patient sample was not tested by all testing personnel.</p>