

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0946312	(X3) Date Survey Completed 10/21/2019
Name of Provider or Supplier David Schwartzwald Md Pa	Street Address, City, State 1601 Clint Moore Rd #195, Boca Raton, 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 conducted on 10/21/2019 found that David Schwartzwald MD PA clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 review of CMS form 209, Laboratory Personnel Report, review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP) A. The laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Chemistry specialty for 2 out of 2 years (2018 - 2019) reviewed. Findings include: Review of CMS form 209 signed by the Laboratory Director (LD) on 8/29/2019 had 2 testing personnel listed (TP A and TP B). Review of API PT records found that TP B, did not perform PT in Chemistry Specialty during 2018 and 2019. During an interview on 10/21/2019 at 9:30 AM, TP A confirmed that TP B missed to participate in PT during the years of above-reference.</p>