

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0990698	(X3) Date Survey Completed 02/04/2021
Name of Provider or Supplier Gina Sevigny Md Pa	Street Address, City, State 305 Clyde Morris Blvd Ste 150, Ormond Beach, 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	At the time of the announced, onsite recertification survey, Gina Sevigny MD was found to be NOT in compliance with the CLIA laboratory requirements of 42 CFR 493. .
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 record review and staff interview, the laboratory failed to rotate proficiency testing to include all testing personnel who perform patient testing for KOH and Scabies for two of two years reviewed (2019-2020). The findings include: Review of the Laboratory Personnel Report (CLIA) CMS 209 revealed that three people performed patient testing on KOH and Scabies specimens (Testing Person #2, #3, and #4). Review of KOH/Scabies proficiency testing worksheets showed Testing Person #4 participated in proficiency testing 8/29/19, 12/31/19, 7/24/20, 8/19/20, and 11/5/20. There was no documentation showing participation from Testing Person #2, and #3. The laboratory policy titled "Parasitology Proficiency Testing Blind Review" states "Our laboratory will perform proficiency testing twice per year (every 6 months) on parasitological procedures to verify testing accuracy." The laboratory policy titled "Mycology Proficiency Testing Blind Review" states "Our laboratory will perform proficiency testing twice per year on mycology procedures to verify testing accuracy. This will be done by using the split sample method and/or by other qualified personnel diagnosing the same sample." During an interview on 2/4/21 with the MOHs technician, it was confirmed that no other Testing Persons other than #4 had performed proficiency testing.</p>