

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0910882	(X3) Date Survey Completed 05/27/2020
Name of Provider or Supplier Elise Chang Hillmann Md Pa	Street Address, City, State 654 W Indiantown Rd Ste 103, Jupiter, 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	An announced recertification survey was conducted on 05/27/20 at Elise Chang Hillmann, M.D., a clinical laboratory in Jupiter, Florida. Elise Chang Hillmann, M.D. was not in compliance with 42 Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory did not verify the accuracy of histology slide interpretation twice annually. Findings include: Review of proficiency testing records on over the past two years on 05/27 /2020 revealed that the laboratory did proficiency testing 12/7/2018, 2/26/2019, and 4 /17/2020. The laboratory did not verify accuracy twice annually in 2018 and 2019. The Peer Review Services Agreement in the procedure manual indicated that three regular derm cases would be sent out for review from an outside laboratory every six months. During an interview with the laboratory director at 10:40 a.m. on 05/27/2020, she confirmed that there was one set of cases sent out for proficiency testing in 2018 and 2019.</p>