

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1007259	(X3) Date Survey Completed 02/11/2021
Name of Provider or Supplier Bay Dermatology And Cosmetic Surgery Pa	Street Address, City, State 7500 Gulf Blvd Ste B, St Pete 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	An announced CLIA recertification survey was conducted at Bay Dermatology and Cosmetic Surgery PA on 02/11/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory director failed to have a personnel competency procedure to evaluate staff competency of those performing high complexity testing for two of two years reviewed (2019-2020). Findings Included: Review of the CMS 209 Laboratory Personnel Report revealed Personnel #A was the Laboratory Director, the Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and high complexity Testing Personnel. Testing Personnel #B performed high complexity testing. Review of employee files revealed that Personnel #B did not have any competency evaluations for histopathology for two out of two years (2019-2020). Interview on 02/11/21 at 12:00 PM with the Office Manager revealed she did not know that competency evaluations for histopathology needed to be performed and the laboratory did not have a competency procedure for those that performed high complexity testing.</p>