

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2037541	(X3) Date Survey Completed 08/17/2022
Name of Provider or Supplier Bay Dermatology & Cosmetic Surgery Pa	Street Address, City, State 7739 S Suncoast Blvd, Homosassa, 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 8/11/22 to 8/17/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to have any Quality Assurance (QA) records for two of two years reviewed (2020-2022). Findings include: Review of laboratory records revealed no QA records were present since the time of the previous recertification survey (5/28/2020). Interview with the Office Manager at 12:15 p.m. on 8/11/22 confirmed that no QA records had been documented.</p>