Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1033712	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Bay Dermatology And Cosmetic Surgery Pa	**Street Address, City, State** 34941 Us Hwy 19 N, Palm Harbor, 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 06/26/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to evaluate the accuracy of testing twice annually for fungi and ectoparasites for two of two years 2023 and 2024 for three of three testing persons (TP #A, B, C). Findings included: 1. The laboratory's Quality Assurance of KOH and Ectoparasite policy, issued 11/10 /2005 was reviewed. The policy stated, "this policy and procedure is to ensure the continued quality performance and results of KOH (fungi) and Ectoparasite procedures and results." The procedure stated, "A program has been set-up to review 1% of the results semi-annually by a dermatologists... All cases that are reviewed are documented on the appropriate review sheet and signed by the reviewing dermatologist." 2. Quality Assurance documentation related to evaluating the accuracy of fungi and ectoparasite testing was reviewed for TP #A, B, and C for 2023 and 2024. None of the TP had completed accuracy evaluations for either test for 2023 or 2024. 3. Interview with the Lab Director on 06/26/2025 at 12:15 p.m., revealed they were not aware the twice annual accuracy verifications for fungi and ectoparasites were not completed for 2023 or 2024.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the established quality assessment program failed to identify the laboratory failed to evaluate the accuracy of testing twice annually for fungi and ectoparasites for two of two years 2023 and 2024 for three of three testing persons (TP #A, B, C). Findings included: 1. (See D5217). 2. Quarterly Quality Assurance Checklists were reviewed from May 2023 through May of 2025, totaling 9 checklists. The checklists were signed by the Lab Director on 05/22/2025, 02/20/2025, 11/14/2024, 08/15/2024, 05/09/2024, 02/15/2024, 11/09/2023, 08/24 /2023, and the May 2023 was signed but undated. Every form documented "Y" or yes for; (A) "Proficiency test results were evaluated, failures were investigated, and corrective action was taken and documented" and (B) "If corrective action was taken, has the problem been corrected over time?" There was no corrective action documented on any for the 9 checklists. 3. Interview with the Lab Director on 06/26 /2025 at 12:15 p.m., revealed they were not aware the twice annual accuracy verifications for fungi and ectoparasites were not completed for 2023 or 2024 and their Quality Assurance did not identify the failure.