Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1007259	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bay Dermatology And Cosmetic Surgery Pa	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 05/22/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5200 493.1230 Condition: General Lab Systems
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of previous survey findings and plan of correction, personnel records, form CMS-209, policy and procedure manual, Quality Assurance documents, and staff interviews, the laboratory failed to assess the competency bi-annually for one testing personnel (B) for four of four competency assessments from 06/2023 through 01/2025 and one testing personnel (C) for 2025 (01/2025) for the subspecialty of Histopathology (See D5209), and the laboratory failed to accurately identify problems via their quality assurance program and failed to identify and address repeated non-compliance regarding testing personnel competency not being completed per their plan of correction and their policy and procedure. (See D5291).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of previous survey findings and plan of correction, personnel records, form CMS-209, policy and procedure manual and staff interviews, the laboratory failed to assess the competency bi-annually for one testing personnel (#B) for four of four competency assessments from 06/2023 through 01/2025 and one testing personnel (#C) for 2025 (01/2025) for the subspecialty of Histopathology. This is a repeat deficient practice from the 02/21/2023 recertification survey. Findings included: 1. The accepted Plan of Correction signed by the Laboratory Director with a correction date of 03/20/2023 for the recertification survey completed 02/21/2023 showed the Laboratory Director would complete bi-annual competency assessments on any testing person performing high complexity testing. The Laboratory Director would complete this in January and June of every year. 2. The Testing Personnel Competency Assessment policy, dated 03/01/2021, reviewed and approved by the Laboratory Director 10/2023 and 10/2024, was reviewed. The policy stated the Laboratory Director would complete competency assessments bi-annually for practitioners performing testing in Histology (Histopathology). 3. The CMS-209, Laboratory Personnel Report, signed and dated 05/22/2025 by the Laboratory Director was reviewed. The form showed testing personnel (TP) #B and #C performed high complexity testing. 4. The Office Manager was interviewed on 05/22/2025 at 10:40 a. m. The Office Manager reported on 05/22/2025 at 10:40 a.m., TP #C began testing in 01/2025 and TP #B had been with the laboratory for several years. 5. TP #B's personnel record was reviewed for 2023 (June), 2024 (January and June), and 2025 (January). No competency assessments for the subspecialty of Histopathology for 2023, 2024 or 2025 were present. TP #C's personnel record failed to contain any competency assessments for the subspecialty of Histopathology for 2025. 6. Interview with the Laboratory Director on 05/22/2025 at 11:30 a.m. confirmed the lack of documented competencies for TP #B and #C performing high complexity testing for the subspecialty of Histopathology.
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 review of Quality Assurance documents and staff interview, the laboratory failed to monitor, identify, and correct repeat non-compliance regarding testing personnel competency from 06/2023 to 05/22/2025 for the subspecialty of Histopathology. Findings included: 1. "Quarterly Quality Assurance Checklist" forms were reviewed. These reviews included checklists signed by the Laboratory Director for January/February/March 2025, September/October/November/December 2024, April/May/June 2024, January/February/March 2024, November/December 2023, August/September/October 2023, and May/June/July 2023. All signed by the Laboratory Director. All checklists documented "Y" (Yes) for: "All personnel who perform specimen collection, handling, testing, and reporting tests have been trained

	and this training has been documented" "Personnel evaluations were performed as necessary..." "Our current personnel policies and procedures are effective" 2. Interview with the Office Manager, acting on behalf of the laboratory, on 05/22/2025 at 1:55 p.m. confirmed the above. 3. See D5209.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory performed testing for the subspecialty of Histopathology when the cryostat temperature was outside of range for five (3/17/25, 6/24/24, 6/25/24, 10/23/23, 10/24/23) out of twenty five days selected for review. Findings included: 1. The "Cryostat Temperature Monitor Log" was reviewed for the following dates when patient testing was performed for the subspecialty of Histopathology; March 3, 4, 7, 10, 14, 17, 21, 24, 25, and 28 of 2025, June 4, 7, 10, 14, 24, 25, and 28 of 2024, and October 6, 9, 13, 20, 23, 24, 27, and 31 of 2023. The form documented the acceptable range for the cryostat was -20 to -28 degrees Celsius. The form documented the temperature of the cryostat as out of range at -19 degrees Celsius on 03/17/25, 06/24/24, 06/25/24, 10/23/23, and 10/24/23. 2. Interview with the Office Manager, acting on behalf of the laboratory, on 05/22/2025 at 1:55 p.m. confirmed the above data.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of Quality Assurance documents and staff interview, the laboratory failed to accurately identify analytic system problems via their quality assurance program when the cryostat temperature was outside of range for five (3/17/25, 6/24 /24, 6/25/24, 10/23/23, 10/24/23) out of twenty five days selected for review. Finding included: 1. "Quarterly Quality Assurance Checklist" forms were reviewed. These reviews included checklists labeled for January/February/March 2025, September /October/November/December 2024, April/May/June 2024, January/February/March 2024, November/December 2023, August/September/October 2023, and May/June /July 2023, all were signed by the Laboratory Director. The forms all documented "Y" (Yes) for "All required temperatures were taken and recorded." There was no documentation to reflect the cryostat temperatures were out of range nor was there any corrective action documented. 2. Interview with the Office Manager, acting on

	behalf of the laboratory, on 05/22/2025 at 1:55 p.m. confirmed the above. 3. See D5413.