Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D2018500	01/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bates Mill Dermatology, Pllc	70 Lincoln Street, Mill 6, Lewiston, ME	

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
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 lack of documentation, record review, and interview with the MOHS Technologist (MT) the laboratory failed to verify the accuracy of MOHS testing twice annually. Findings: 1. Record review of the laboratory's proficiency testing documentation for 2023 and 2024 on 1/15/2025, revealed no documentation for the twice annual verification of Mohs testing. 2. Record review of the laboratory's Proficiency Testing policy on 1/15/2025 revealed: "Semi-Annually, The tech or Risk Manager will send two cases containing the original slides... send it our for a microscopic examination by a Board Certified Dermatopathologist... Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of it's permanent records." 3. Interview with the MT on 1/15/2025 at 10:00am confirmed the findings above. 4. The laboratory performs 962 tests annually in the specialty of Pathology.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory MOHS Technologist (MT) the laboratory failed to assure function checks were within the laboratory's established limits before patient testing. Findings include: 1. Record review on 1/15/25 of 2024 and 2025 Cryostat temperature logs revealed the following: a. Temperature ranges, top of page: -21C to -25C and, lower on the page, -21*C to -26*C. b. The temperature states, "Notify director of any problems with the machine and document." c. The cryostat was noted as having temperatures lower than the established ranges on testing days 2024: 8 of 19 January, 12 of 13 February, 8 of 9 March, 13 of 14 April, 9 of 12 May, 7 of 11 June, 5 of 12 November, 4 of 11 December, and 2025: 3 of 5 January. Temperatures were lower than established ranges 2024: 4 of 11 June, 3 of 13, 2 of 15 September. 3. Interview with the MT on 1/15/2025 at 9:30am confirmed the above findings. The MT stated that the lab director had been made aware of the temperature variations but no corrective action had been documented. 4. The laboratory performs 962 tests annually in the specialty of Pathology.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on record review and interview with the MOHS Tech (MT), the laboratory failed to ensure corrective action policies and procedures were available and followed within the laboratory. Findings include: 1. Record review on 1/15/25 of 2024 and 2025 Cryostat temperature logs revealed the following: a. Temperature ranges, top of page: -21C to -25C and, lower on the page, -21*C to -26*C. b. The temperature states, "Notify director of any problems with the machine and document." c. The cryostat was noted as having temperatures lower than the established ranges on testing days 2024: 8 of 19 January, 12 of 13 February, 8 of 9 March, 13 of 14 April, 9 of 12 May, 7 of 11 June, 5 of 12 November, 4 of 11 December, and 2025: 3 of 5 January. Temperatures were lower than established ranges 2024: 4 of 11 June, 3 of 13, 2 of 15 September. 2. Record review of the MOHS laboratory procedure manual on 1/15 /2025 revealed: a. The laboratory did not have a policy or procedure for corrective action when Cryostat temperatures were out of range. b. Corrective action was not documented when the above temperatures were out of range. 3. Staff interview with the MT on 1/15/2025 at 9:00am confirmed the findings above. 4. The laboratory performs 962 tests annually in the specialty of Pathology.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on lack of documentation, record review and staff interview, the Laboratory

	Director failed to provide management and rection in accordance with the Federal CLIA regulations 493.1445. Refer to D6079, D6087, D6093, D6096 and D6106.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Refer to Refer to D6087, D6093, D6096, D6106
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Refer to 5217
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to ensure quality control and quality assessment (QA)programs were maintained to assure the quality of laboratory services. Findings include: 1. Record review of the laboratory QA policy on 1/15/2025 revealed: "The (QA) checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems. Any discrepancies found in the checklist for the month will be documented... The lab director will also review and sign off the checklist monthly." 2. Record review of quality documentation for 2023 and 2024 on 1/15/2025 revealed no QA checklist. 3. Interview with the MOHS Technologist on 1/15/2025 at 9:00am confirmed the above findings. 4. The laboratory performs 962 tests annually in the specialty of Pathology.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Refer to 5779.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Refer to 5779.