Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089628	02/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Chapman Laboratory	200 Somerset Street, Millinocket, 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
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 staff interview, it was determined that the laboratory did not have a quality systems policy for monitoring, assessing, and corrective action in the specialty of hematology. Findings include: 1. Record review of the laboratory hematology freezer temperature documentation on 2/25/2026 revealed temperatures to be out of range 124 days from January 2024 to June 2025 with no corrective action completed. 2. Staff interview with the Technical Consultant/Technical Supervisor (TC /TS) on 2/25/2026 at 10:00am confirmed the findings above. The TC/TS noted that testing personnel had not informed the TC/TS of the issue and that the lab director had also not been informed. The TC/TS additionally noted that they had signed the log as reviewed. 3. The laboratory performs 53,816 tests annually in the specialty of hematology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the reference range for Nucleated Red Blood Cells (NRBC) on the laboratory's final patient test report did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's NRBC reference ranges for patient #1 (female) with the laboratory's procedure for the Sysmex XN-1000 Hematology Analyzer revealed the following: a. Final report: NRBC % 0.00-0.01 % b. Procedure: NRBC % 0-0.2 % c. Final report NRBC # 0.0-0.1 10^3/ul d. Procedure NRBC # 0-1.012 x 10^3/ul 2. Staff interview with the practice manager on 2/26/2026 at 9:00am confirmed the reference ranges for NRBC female did not correlate with the reference ranges on the final patient test report. 3. The laboratory performs 53,813 tests annually in the specialty of Hematology.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the Technical Consultant #1 and #2 failed to ensure remedial action when the test system deviated from established specifications. Refer to 5291