Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089835	01/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mount Desert Island Hospital Laboratory	10 Wayman Lane, Bar Harbor, 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
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 ranges for the Red Cell Distribution Width - Standard Deviation (RDW-SD) and the Mean Platelet Volume (MPV) on the laboratory's final patient test report did not correlate with the reference ranges in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's RBC reference range for patient #1 (female) with the laboratory's procedure for Hematology Reporting Results revealed the following: RDW-SD: a. Final report: 35.0-47.0 fL b. Reporting Results:

	35-43.9 fL MPV: a. Final report: 8.5-12.0 fL b. Reporting Results: 1.9-7.8 fL 2. Staff interview with the Technical Supervisor on 1/28/2026 at 12:00 PM confirmed the above findings. 3. The laboratory performs 72,425 tests annually in the specialty of Hematology.