Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089891	05/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Down East Community Hospital	11 Hospital Drive, Machias, 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 Chemistry and Hematology on the laboratory's final reports did not correlate with the reference ranges in the laboratory's procedure manuals. Findings include: 1. Comparison on 5/15/2025 of final reported Chemistry reference ranges with the laboratory procedure for chemistry revealed the following: a. Reported Vancomycin: 10.0-20 g/mL. Procedure: Variable dependent on both "dosage regimen and timing of sample collection". b. Reported Ammonia: 16.0-53.0 mmol/L.

	Procedure: 18-72 mol/L c. Reported Creatinine Kinase 38.0-234.0 IU/L. Procedure: 49-397 U/L d. Reported Salicylate 4.0-20.0 mg/dL. Procedure: Variable dependent on treatment. e. Reported Digoxin 0.5-2.0 ng/mL. Procedure: 0.8-2.0 ng/mL 2. Review of the Hematology procedure manual on 5/15/2025 revealed no documented reference values. 3. Staff interview with the Technical Supervisor on 5/15/2025 at 9:00am confirmed the findings above. 4. The laboratory performs 261,405 tests annually in the specialty of Chemistry and 99,006 tests annually in the specialty of Hematology.
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: Based on record review and interview with Technical Supervisor (TS1), the laboratory director failed to document the approval of Hematology procedure manual reference ranges. Findings include: 1. Record review of the laboratory's Hematology procedure manual on 5/15/2025 revealed no documented reference ranges. 2. Staff interview with TS1 on 5/15/2025 at 9:00 am revealed the staff to be using a consultant provided reference range handout that was not part of the Hematology procedure manual. 3. The laboratory performs 99,006 tests annually in the specialty of Hematology.