

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0693460	(X3) Date Survey Completed 09/05/2025
Name of Provider or Supplier Sebasticook Valley Health	Street Address, City, State 447 North Main Street, Pittsfield, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory manual failed include the reportable range for test results for the Siemens Dimension chemistry analyzer. Findings include: 1. Record review of the laboratory chemistry manual on 9/4/2025 revealed no reference ranges for the Siemens Dimension chemistry analyzer. 2. Record review of a reference range sheet being used for the Siemens Dimension chemistry analyzer on 9/4/2025, revealed no written approval by the Laboratory director. 3. Interview with the Technical Consultant on 5/4/2025 at 11:00am</p>

	<p>confirmed the findings above. 4. The laboratory performs 79,659 tests per year in the specialty of Chemistry.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to sign and date the Siemens Dimension chemistry analyzer reference ranges prior to use. Refer to D5403.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS), the TS failed to evaluate competency of testing personnel (TP) for routine test performance. Findings include: 1. Record review on 9/4/2025 of the laboratory's TP competency records revealed: a. 8 of 8 TP did not have their competency completed by the TS. b. TP were reviewing each other without being delegated as General Supervisors. 2. Staff interview with the TS on 9/4/25 at 10:00 AM confirmed the above findings. 3. The laboratory performs 105,970 tests annually.</p>