Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089610	01/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Penobscot Valley Hospital	7 Transalpine Road, Lincoln, 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 Immunohematology Findings include: 1. Record review of the laboratory Immunohematology procedure manual on 1/24/2025 revealed no quality assessment Blood Bank Alarm system policy. 2. Staff interview with the Technical Supervisor (TS) on 1/24/2025 at 10:00am confirmed the findings above. The TS noted that there was a policy but it could not be found. 3. The laboratory performs 591 tests annually in the specialty of Immunohematology.
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 Hematology RDW (Red Cell Distribution Width) Microbiology Trichomonas, and Chemistry ALT (Alanine Transaminase) on final patient test reports did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test reports on 1/22/2025 with the laboratory's Chemistry and Hematology procedures revealed the following: Patient #1 (Female) a. Final report: RDW 36.5-46.3 f/L b. Procedure: RDW-CV 11.5-13.5 Patient #2 (Male) a. Final report: ALT 16-63 U/L b. Procedure: ALTI 14-63 U/L Patient #3 (Female) a. Final report: "Trichomonas None" b. Procedure: Report Trichomonas as POSITIVE (seen) or NEGATIVE (none seen). 2. Staff interview with the Technical Supervisor on 1/23/2025 at 9:30am confirmed the reference ranges did not correlate with data on the final patient test reports. 3. The laboratory performs 119,035 tests annually in the specialty of Chemistry, 6.072 tests annually in teh specialty of Microbiology, and 41,378 tests annually in the specialty of Hematology.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, it was determined that the laboratory director (LD) had not signed the laboratory's Chemistry procedure manual, Hematology Manual, or I-Stat manual. Findings include: 1. Record review of the Chemistry, Hematology, and I-Stat procedure manuals on 1/23/2025 revealed the LD had not signed the manuals. 2. Staff interview with the Technical Supervisor on 1 /23/2025 at 9:00am confirmed the findings above. 3. The laboratory performs 119,035 tests annually in the specialty of Chemistry and 41,378 tests annually in the specialty of Hematology.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the laboratory failed to ensure the Blood Bank refrigerator alarm system was functioning per regulation in the specialty of Immunohematology. Refer to: D6119
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the Technical Supervisor (TS) did not ensure that corrective action was taken and the test system functioning properly in the specialty of Immunohematology. Findings include: 1. Record review of the laboratory Immunohematology preventative maintenance documentation on 1/24/2025 revealed the Blood Bank refrigerator alarm system quarterly maintenance had not been performed in September 2024 due to an alarm system failure from 8/13/2024 - 9/14/2024. 2. Record review of the "Temperature Control" policy on 1/24/2025 revealed the following: "Backup Storage 17.0 Refrigerator contents are moved to other refrigerator storage..." 3. Interview with the TS on 1/24/2025 at 10:00am confirmed the findings above. The TS noted that the American Association of Blood Banks requires a failed alarm system to be monitored every 4 hours, but this process was not instituted at the time of failure, blood products were not moved, and a corrective action investigation not performed until 1/17/2025. 4. The laboratory performs 591 tests annually in the specialty of Immunohematology.