Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089610	11/03/2022
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 Chemistry 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 Comprehensive Panel Chemistry reference ranges for patient #1 (female) with the laboratory's procedure for Chemistry revealed the following: a. Final report: Calcium 8.5-10.1 mg/dl Creatinine 0.60-1.00 mg/dl Glucose 70-99 mg/dl b. Chemistry procedure: Calcium 5-14 mg/dl Creatinine 0-20 mg /dl Glucose 0-500 mg/dl 2. Record review of the laboratory's Quality Assessment

	policy LAB-301 on 11/3/2022 revealed the statement: "Policies and procedures are reviewed annually." 3. Staff interview with the technical supervisor on 11/3/2022 at 9: 30AM confirmed the reference ranges in the laboratory manual did not correlate with the reference ranges on the final patient test report. 4. The laboratory performs 110,379 tests annually in the specialty of chemistry.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on maintenance record review and interview with the technical supervisor (TS) the laboratory failed to document routine maintenance and function checks for laboratory equipment for compliance and waived testing. Findings include: 1. Record review of the Siemens EXL, 2021 and 2022 maintenance logs on 11/03/2022 revealed the laboratory failed to document weekly maintenance and function checks for the 6 or 12 months from October 2021-October 2022. 2. Record review of the GeneXpert, 2022 maintenance logs on 11/03/2022 revealed the laboratory failed to document maintenance and function checks for the 4 of 9 months from February 2022-October 2022. 3. Staff interview with the TS on 11/3/2022 at 10:00AM confirmed the above findings. 4. The laboratory performs 110,379 tests annually in the specialty of Chemistry and 8,490 waived tests.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on staff interviews and record review of quality assurance documentation the laboratory failed to implement effective policies and procedures to prevent the reoccurring problem of failure to document maintenance and function checks. Findings include: 1. Refer to tag 5429. 2. Staff interview with the Technical Supervisor (TS) on 11/3/2022 at 10:30AM revealed that the TS was aware of an ongoing quality documentation issue but had not rectified the issue. 3. The laboratory performs 110,379 tests annually in the specialty of Chemistry and 8,490 waived tests.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS), the laboratory director failed to document the approval of the IQCP in the specialty of microbiology. Findings include: 1. Record review of the laboratory's IQCP on 11/03 /2022 revealed the policy was not approved or annually reviewed by the laboratory director. 2. Record review of the laboratory's Quality Assessment policy LAB-301 on 11/3/2022 revealed the statement: "Policies and procedures are reviewed annually." 3. Staff interview with the TS on 11/3/2022 at 11:00 AM confirmed the above findings. 4. The laboratory performs 8,618 compliance level tests per year under the specialty of Microbiology.