

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089610	(X3) Date Survey Completed 09/03/2025
Name of Provider or Supplier Penobscot Valley Hospital	Street Address, City, State 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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing reports from the laboratory. The facility was found to be out of compliance with the conditions of the CLIA program. The following: CONDITION and STANDARD level deficiencies were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation proficiency testing D2118- 42 C.F.R. 493.845 Standard: Laboratories performing Moderate Complexity testing: Chemistry
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the proficiency testing (PT) data report (Casper Report 155D) and

	staff interview, the laboratory failed to successfully participate for the regulated analyte Acetaminophen Serum. Refer to D2118.
D2118	TOXICOLOGY CFR(s): 493.845(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on Review of the CASPER Proficiency Testing (PT) data report (155), and staff interview, the laboratory failed to successfully participate in PT for Chemistry. Findings include: 1. Record review on 8/29/2025 of the CASPER 155 report revealed scores of 60% for CAP 2025 Event 1 and 2025 Event 2, that were unsatisfactory for the regulated analyte: Acetaminophen Serum. 2. Email correspondence from the laboratory director of services on 9/3/2025 confirmed the findings above. 3. The laboratory performs 119,035 tests annually in the specialty of Chemistry.