

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089610	(X3) Date Survey Completed 10/15/2021
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	A proficiency testing desk review of the Penobscot Valley Hospital Laboratory was conducted on 10/15/21 pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview with the laboratory manager (LM), the laboratory director (LD) failed to sign the attestation sheet for the College of American Pathologists (CAP) proficiency testing (PT) samples in the subspecialty of bacteriology. Finding include: 1. Record review on 10/15/2021 of the laboratory's PT attestation sheets for CAP Bacteriology Survey D-B 2021 revealed the LD did not sign the attestation sheet. The attestation sheet was signed by the LM who does not qualify as a technical supervisor. 2. Staff interview on 10/15/2021 with the LM confirmed the above findings. 3. The laboratory performs 4,675 tests annually in the specialty of microbiology.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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,</p>

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 PT graded results from the College of American Pathologists (CAP), the laboratory failed to successfully participate for the regulated analyte Bacteriology. Refer to D2028.

D2028

BACTERIOLOGY

CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for 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 proficiency testing (PT) data reports (Casper Report 155D) and PT graded results from the College of American Pathologists (CAP) , the laboratory failed to successfully achieve a score of 80 percent (%) in two of three testing events for the subspecialty of bacteriology. Findings include: 1. Record review on 10/15 /2021 of the Center for Medicare & Medicaid Services (CMS) CASPER 0155D report revealed the laboratory obtained unsatisfactory scores for two of three consecutive PT events for analyte 0005 bacteriology as follows: a. 2020 - Event 3 - 83% b. 2021 - Event 1 - 76% c. 2021 - Event 2 - 70% 2. Record review on 10/15/2021 of the College of American Pathologists PT program results for the 2021 Bacteriology Survey D-A event 1 and D-B event 2 revealed the laboratory obtained unsatisfactory scores in two of three consecutive PT events as evidenced below. a. 2021 - Event 1 - 76% b. 2021 - Event 2 - 70% The laboratory performs 4,675 tests annually in the specialty of microbiology.