

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089891	(X3) Date Survey Completed 09/20/2022
Name of Provider or Supplier Down East Community Hospital	Street Address, City, State 11 Hospital Drive, Machias, 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
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, 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.</p> <p>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 American Proficiency Institute (API), the laboratory failed to successfully participate for the regulated analyte Bacteriology. Refer to D2028.</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>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</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) desk review, 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 9/20/2022 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. 2021 - Event 3 - 78% b. 2022 - Event 1 - 100% c. 2022 - Event 2 - 78% 2. Record review on 9/20/2022 of the American Proficiency Institute PT program results for the 2021 Bacteriology Survey event 3 and the 2022 survey event 2 revealed the laboratory obtained unsatisfactory scores in two of three consecutive PT events as evidenced below. a. 2021 - Event 3 - 78% b. 2022 - Event 2 - 78% 3. Interview correspondence on 9/19/2022 with the laboratory manager confirmed the above findings. 4. The laboratory performs 1,804 tests annually in the specialty of Microbiology.