

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1095814	(X3) Date Survey Completed 04/05/2023
Name of Provider or Supplier New England Urology	Street Address, City, State 900 Cummings Ctr, Beverly, MA	
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 CLIA paper desk review of proficiency testing was conducted for the the New England Urology laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the subspecialty area of Bacteriology, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
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 proficiency testing review for calendar years 2022 and 2023, (three testing events), the laboratory failed to successfully participate (achieve a score of 80 percent</p>

or more) in a proficiency testing program for the subspecialty of Bacteriology . The laboratory achieved a score for Bacteriology of zero (0) percent (failure to participate - refer to D2021) for the second testing event of 2022 and the first testing event of 2023. .

D2021

BACTERIOLOGY
CFR(s): 493.823(b)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

. Based on American Proficiency institute (API) proficiency testing record review on 4/4/23 for calendar years 2022 and 2023 (three testing events) and interview, the laboratory failed to participate in the second testing event of 2022 as well as the first testing event of 2023 for the subspecialty area of Bacteriology resulting in unsatisfactory performance and a score of zero (0) percent for each of the two testing events. The technical consultant confirmed in an email on 4/4/23 that the laboratory had stopped testing due to lack of personnel. However, this notification to the State agency was after the issuance of scores by the proficiency testing provider and there was no prior to notification to the state agency regarding cessation of Bacteriology testing. .