

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D1095814	<b>(X3) Date Survey Completed</b>  11/28/2018
<b>Name of Provider or Supplier</b>  New England Urology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial CLIA certification survey was conducted for the New England Urology laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 (PT) review and interview, the laboratory failed to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the human chorionic gonadotropin (hCG) analyte as evidenced by the following: a. The laboratory utilizes American Proficiency Institute (API) for PT. b. A review of two (2) testing events for 2018 revealed the laboratory achieved a score</p>

	<p>of forty (40) percent for the second event and a score of zero (0) percent for the third event. c. The technical consultant confirmed through interview on 11/28/18 at 11 AM that the laboratory failed to successfully participate in PT for hCG. (Refer to D2098 &amp; D2107)</p>
<p><b>D2098</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review and interview, the laboratory failed to attain a score of least eighty (80) percent in the American Proficiency Institute (API) proficiency testing (PT) program for the human chorionic gonadotropin (hCG) analyte as evidenced by the following a. The laboratory achieved a testing event score for the hCG analyte of forty (40) percent for the second testing event of 2018. b. The laboratory achieved a testing event score for the hCG analyte of zero (0) percent (failure to participate) for the third testing event of 2018. c. The technical consultant confirmed through interview on 11/28/18 at 11 AM that the laboratory failed to attain a score of at least eighty (80) percent in each testing event for hCG.</p>
<p><b>D2107</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview, the laboratory failed to achieve satisfactory performance for the human chorionic gonadotropin (hCG) analyte as evidenced by the following: a. The laboratory achieved an overall testing event score for the hCG analyte of forty (40) percent for the second testing event of 2018 and a score of zero (0) percent (failure to participate) for the third testing event of 2018 resulting in the first instance of unsuccessful performance for the subspecialty of Endocrinology. b. The technical consultant confirmed through interview on 11/28/18 at 11 AM that the laboratory failed to achieve satisfactory performance for the hCG analyte in two consecutive testing events</p>