

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1095814	(X3) Date Survey Completed 09/03/2019
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 on 9/3/19 for 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 a second occurrence of unsuccessful proficiency testing performance for the human chorionic gonadatropin (hCG) analyte, the following Condition level deficiencies were deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. Condition 42 CFR 493.1403 - Laboratory Director. .
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:</p>

Based on record review on 9/3/19 of calendar years 2018 and 2019 proficiency testing results (four testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the American Proficiency Institute (API) proficiency testing program for the Human Chorionic Gonadotropin (hCG) analyte as evidenced by the following First Unsuccessful Occurrence: The laboratory achieved a testing event score for the the subspecialty of Endocrinology of forty (40) percent for the second testing event of 2018 and a score of zero (0) percent (failure to participate - refer to D2100) for the third testing event of 2018 resulting in the first instance of unsuccessful performance for the the subspecialty of Endocrinology and the hCG analyte . Second Unsuccessful Occurrence: The laboratory achieved a testing event score for the the subspecialty of Endocrinology of zero (0) percent (failure to participate - refer to D2100) for the third testing event of 2018 and a score of sixty (60) percent for the second testing event of 2019 resulting in the second instance of unsuccessful performance for the the subspecialty of Endocrinology and the hCG analyte. It was confirmed in an email interview on 9/3/19 with the technical consultant that the laboratory was unsuccessful in the proficiency testing events listed above. Based on this evidence the laboratory failed to undertake the appropriate training and /or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the hCG analyte in the subspecialty of Endocrinology. Refer to D2100, D2105, and D2107. .

D2100

ENDOCRINOLOGY
CFR(s): 493.843(c)

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 proficiency testing record review for calendar years 2018 and 2019 (four testing events), the laboratory failed to participate in the third testing events of 2018 resulting in a score of zero (0) for the proficiency testing event for the Human Chorionic Gonadotropin (hCG) analyte. .

D2105

ENDOCRINOLOGY
CFR(s): 493.843(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on record review on 9/3/19 of calendar years 2018 and 2019 proficiency testing results (four testing events), the laboratory failed to undertake effective remedial action in response to unsatisfactory American Proficiency Institute proficiency testing program testing results for the Human Chorionic Gonadotropin (hCG) analyte as evidenced by the following: First Unsuccessful Occurrence: The laboratory achieved a 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 return results within the time frame specified - refer to D 2100) for the third testing event of 2018 resulting in the first instance of unsuccessful performance for the hCG analyte. Second Unsuccessful Occurrence: The laboratory achieved a testing event score for the hCG analyte of zero (0) percent (failure to return results within the time frame specified - refer to D 2100) and a score of sixty (60) percent for the second testing event of 2019 resulting in the second instance of unsuccessful performance for the hCG analyte. Based on a second occurrence of unsuccessful proficiency testing for the hCG analyte the laboratory failed to undertake the appropriate training and/or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the hCG analyte.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(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 proficiency testing (PT) record review and interview, the laboratory failed to achieve satisfactory performance for the human chorionic gonadatropin (hCG) analyte resulting in two unsuccessful proficiency testing events as evidenced by the following: First unsuccessful occurrence: The laboratory achieved an overall testing event score for hCG 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 hCG analyte. Second unsuccessful occurrence: The laboratory achieved an overall testing event score for hCG of zero (0) percent (failure to participate) for the third testing event of 2018 and a score of sixty (60) percent for the second testing event of 2019 resulting in the second instance of unsuccessful performance for the hCG analyte. It was confirmed in an email interview on 9/3/19 with the technical consultant that the laboratory was unsuccessful in the proficiency testing events listed above. .

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency

testing results resulting in the second unsuccessful performance for the Human Chorionic Gonadotropin (hCG) analyte (refer to D2016).