Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1095814	07/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
New England Urology	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 recertification 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. .
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with the technical consultant (TC) on 7/28/21, the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for the General Immunology subspecialty for which it seeks certification as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records from calendar years 2019, 2020, and 2021on 7 /28/21. The review revealead that the laboratory did not enroll in an HHS approved PT testing program for the General Immunology subspecialty test Alpha Fetoprotein (AFP). The TC confirmed in an interview on 7/28/21 at 10:05 AM that the laboratory failed to enroll in an HHS approved PT program for General Immunology. The laboratory performs approximately 100 AFP tests annually. (Refer to D6041) .
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 record review and interview with the TC on 7/28/21, the laboratory failed to participate in PT events resulting in a score of zero (0) percent for the Bacteriology specialty. Findings include: The surveyor reviewed API PT records on 7/28/21 for calendar years 2019, 2020, and 2021. The review revealed that the laboratory failed to participate in the Bacteriology third event in 2019. The TC confirmed in an interview 7 /28/21 at 10:00 AM that the laboratory failed to participate resulting in a score of zero (0) percent for the third Bacteriology testing event in 2019. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview on 7/28/21 with the TC, the laboratory failed to verify the accuracy of tests twice annually. Findings include: The surveyor reviewed API PT records for calendar years 2019, 2020, and 2021. The review revealed: 1. The laboratory was not enrolled in API PT for Sex Hormone Binding Globulin (SHBG). The laboratory failed verify the accuracy of SHBG at least twice annually in 2019, 2020, and 2021. 2. In 2019, API provided 2 testing events for Endocrinology tests. The laboratory scored 0% (Failed to Participate) in 2019 Event 2 for Estradiol, Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Parathyroid Hormone (PTH), Prolactin, Prostate Specific Antigen (PSA), and 25-hydroxyvitamin D. The laboratory failed to verify the accuracy of these tests twice annually in 2019. 3. Free Prostate Specific Antigen (PSA): The laboratory scored 67% in 2019 Event 1 and 0% 2019 Event 2 (Failed to Participate). The laboratory failed to verify the accuracy of PSA twice annually in 2019. 4. Parathyroid Hormone (PTH): The laboratory scored 50% in 2020 Event 1, 0% in 2020 Event 2, and 0% in 2020 Event 3 (Failed to Participate). The laboratory failed to verify the accuracy of PTH twice annually in 2020. 5. Testosterone: The laboratory scored 50% in 2020 Event 1 and 0% in 2020 Event 3 (Failed to Participate). The laboratory failed to verify the accuracy of Testosterone twice annually in 2020. 6. Trichomonas Vaginalis (TV): The laboratory scored 60% in 2019 Event 2 and 0% in 2019 Event 3 (Failed to Participate). The laboratory failed to verify the accuracy of TV twice annually in 2019. The TC confirmed in an interview on 7/28/21 at 10:00 AM that the laboratory failed to verify the accuracy of Endocrinology and Parasitology tests at least tests twice annually. The laboratory performed approximately 20,540 Endocrinology tests and approximately 250 Parasitology tests annually. .

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: . Based on record review and interview on 7/28/21 with the TC, the laboratory failed to perform and document review of all unsatisfactory scores and corrective actions for PT. Finding include: The surveyor reviewed API PT records for calendar years 2019, 2020, and 2021 on 7/28/21. The review revealed that corrective actions were not performed and documented for the following unsuccessful PT results: 1. 2019 Event 1: Free Prostate Stimulating Antigen (PSA) score of 67%. 2. 2019 Event 2: Endocrinology subspecialty score of 0%, Failed to Participate. 3. 2019 Event 2: Trichomonas Vaginalis (TV) score of 60%. 4. 2019 Event 3: Trichomonas Vaginalis (TV) score of 0%, Failed to Participate. 5. 2019 Event 3: Bacteriology Subspecialty score of 0%, Failed to Participate. 6. 2020 Event 1: Parathyroid Hormone (PTH) and Testosterone score of 50%. 7. 2020 Event 2: Parathyroid Hormone (PTH) score of 0%. 8. 2020 Event 3: Endocrinology subspecialty score of 0% and TV score of 0%, Failed to Participate. The TC confirmed in an interview on 7/28/21 at 10:00 AM that corrective actions were not performed and documented for unsuccessful PT results. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the TC on 7/28/21, the laboratory director (LD) failed to ensure that the laboratory was enrolled in an HHS approved PT program for the testing performed. Findings include: The surveyor reviewed API PT records on 7/28/21 for calendar years 2019, 2020, and 2021. The review revealed that the LD failed to enroll in an HHS approved PT program for the General Immunology AFP testing. The TC confirmed in an interview 7/28/21 at 10:00 AM that the LD failed to enroll in PT for AFP. (Refer to D2000) .
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: . Based on record review and interview on 7/28/21 with the TC, the laboratory director (LD) failed to ensure an approved corrective action if followed when PT results are unacceptable or unstisfactory. Finding include: The surveyor reviewed API PT records for calendar years 2019, 2020, and 2021 on 7/28/21. The review revealed that corrective actions were not performed and documented for the following unsuccessful PT results: 1. 2019 Event 1: Free Prostate Stimulating Antigen (PSA) score of 67%. 2. 2019 Event 2: Endocrinology subspecialty score of 0%, Failed to Participate. 3. 2019 Event 2: Trichomonas Vaginalis (TV) score of 60%. 4. 2019 Event 3: Trichomonas Vaginalis (TV) score of 0%, Failed to Participate. 5. 2019 Event 3: Bacteriology Subspecialty score of 0%, Failed to Participate. 6. 2020 Event 1: Parathyroid Hormone (PTH) and Testosterone score of 50%. 7. 2020 Event 2: Parathyroid Hormone (PTH) score of 0%. 8. 2020 Event 3: Endocrinology subspecialty score of 0% and TV score of 0%, Failed to Participate. The TC confirmed in an interview on 7/28/21 at 10:00 AM that corrective actions were not performed and documented for unacceptbale and unsatisfactory PT results. (Refer to D5221) .
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: . Based on record review and interview on 7/28/21 with the TC, the TC failed to ensure the laboratory participated in an HHS approved PT program. Findings include: The surveyor reviewed API PT records on 7/28/21 for calendar years 2019, 2020, and 2021. The review revealed: 1. The TC failed to enroll in an HHS approved PT program for the General Immunology subspecialty. (Refer to D2000). 2. The laboratory failed to participate in the Bacteriology third event in 2019. (Refer to D2021). The TC confirmed in an interview 7/28/21 at 10:00 AM that the TC failed to enroll in PT for General Immunology and the laboratory failed to participate in PT for the subspecialty of Bacteriology.