

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1095814	(X3) Date Survey Completed 12/21/2022
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 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) review and interview with Technical Consultant (TC) on 12/21/2022, the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar years 2021 and 2022 (6 testing events). The review revealed that signed attestation statements provided by the PT program were not available for the following events: Seven (7) out of sixteen (16) attestation statements were not signed by the analyst and the laboratory director: 1. API Chemistry Core 2021 Events 1, 2, and 3. 2. API Microbiology 2021 Events 1, 2, and 3. 3. API Chemistry Miscellaneous 2022 Event 2. The TC confirmed in an interview on 12/21/2022 at 11:00 AM that not all attestation statements were signed by the analyst and laboratory director. The laboratory performs 1000 bacteriology tests, 200</p>

parasitology tests, 1000 general immunology tests, and 11,100 chemistry tests annually. .

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a record review, manufacturer's instructions, and interview with the Technical Consultant (TC) on 12/21/2022, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for two (2) of two (2) analyzers as evidenced by the following: The surveyor reviewed maintenance records for the two (2) analyzers. The review revealed the following findings: (1) On 12/21/2022 at 10:40 am, the TC stated the following: (a) Estradiol, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), PRL (Prolactin), PSA (Prostate Specific Antigen), PTH (Parathyroid Testing Hormone), SHBG (Sex Hormone Binding Globulin), Testosterone, And Vitamin D testing were performed on the Beckman-Coulter Access II analyzer; (b) Chlamydia and Gonorrhea (CT/NG) and Trichomonas vaginalis (TV) testing were performed on the Cepheid GeneXpert analyzer. (2) On 12/21/2022, a review of the manufacturer's maintenance requirements identified the following: (a) Beckman Coulter Access 2 (i) Weekly (aa) Clean Instrument Exterior (bb) Inspect Liquid Waste Bottle (cc) Check Waste Filter Bottle (dd) Inspect/Clean Primary Probe (ee) Replace/Clean Aspirate Probes (b) Cepheid GeneXpert (i) Weekly (aa) Power Down the GeneXpert instrument (bb) Power Down the GeneXpert computer (ii) Quarterly (aa) Clean plunger rod and cartridge bays (3) A review of maintenance records between August 2021 through December 2021 revealed the following: (a) Beckman Coulter Access 2 (i) Weekly maintenance had not been documented as performed between: (aa) 08/23/2021 and 09/07/2021 (bb) 08/17/2021 and 09/29/2021 (b) Cepheid GeneXpert (i) Weekly maintenance had not been documented as performed between: (aa) 08/12/2021 and 08/23/2021 (bb) 09/17/2021 and 09/29/2021 (ii) Quarterly maintenance had not been documented as performed between: (aa) 06/11/2021 and 12/18/2021 The TC confirmed in an interview on 12/21/2022 at 12:04 PM that the laboratory failed to document the maintenance tasks as performed. The laboratory performs 1000 bacteriology tests, 200 parasitology tests, 1000 general immunology tests, and 11,100 chemistry tests annually. .

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be

established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on quality control (QC) record review and interview with Technical Consultant (TC) on 12/21/2022, the laboratory did not verify the new lot number of control material as evidenced by the following: The surveyor reviewed QC records for the Beckman-Coulter Access II Analyzer. The review revealed that the new lot numbers of control material were not verified for the Biorad Lyphocheck Immunoassay Plus Control Lot #'s 40401 and 40403 when the new lot numbers were placed in service on 11/17/2022. QC was not verified for seven (7) of the ten (10) chemistry analytes: Estradiol, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), PRL (Prolactin), Total PSA (Prostate Specific Antigen), Free PSA (Prostate Specific Antigen), and Total Testosterone and the one (1) of one (1) immunology analyte: AFP (Alpha-Fetoprotein). The TC confirmed in an interview on 12/21/2022 at 1:20 PM that the laboratory failed to verify the new lot numbers of control material for seven (7) chemistry analytes and one (1) immunology analyte tested on the Beckman-Coulter Access II Analyzer. The laboratory performs 11,100 chemistry tests and 1,000 immunology tests annually. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on personnel competency record review and interview with the Technical Consultant (TC) on 12/21/2022, the TC failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for the personnel competency records for review. The review revealed that annual competency evaluations were not performed and documented at least annually for one (1) out of the one (1) newly hired testing person (TP) after the first year of performing moderate complexity testing. The TC confirmed in an interview on 12/21/2022 at 9:34 AM that the TC failed to perform and document an annual competency evaluation for one (1) of the newly hired TP's after the first year of performing moderate complexity testing. The laboratory performs 1000 bacteriology tests, 200 parasitology tests, 1000 general immunology tests, and 11,100 chemistry tests annually.