

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0907996	(X3) Date Survey Completed 06/29/2023
Name of Provider or Supplier Urology Associates Of Cape Cod, Pc	Street Address, City, State 125 Route 6a, Yarmouth Port, 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 Urology Associates of Cape Cod laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Clinical Manager (CM) on 6/29 /2023, the laboratory failed to monitor and document temperature conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting as evidenced by the following: The surveyor asked to review the temperature records for the refrigerator, freezer, and room temperature for high complexity PCR testing for calendar years 2022 and 2023. The record review revealed that the laboratory was missing temperature records for September 2022, October 2022, November 2022, December 2022, January 2023, and February 2023. The CM confirmed in an interview on 6/29/2023 at 12:50 PM that the laboratory failed to maintain documentation of the laboratory's refrigerator, freezer, and room temperatures for the six (6) months from September 2022 to February 23, 2023. The laboratory performs 1,170 Microbiology tests annually. .</p>
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 record review and interview with the Clinical Manager (CM) on 6/29/2023, the laboratory failed to document maintenance of analyzers defined by the manufacturer and with at least the frequency specified by the manufacturer as evidenced by the following: The surveyor asked to review maintenance records required by the manufacturer for the Quant Studio 5/King Fisher Thermo analyzer since the analyzer was implemented on 4/09/2022. The review revealed that the recommended weekly maintenance was not performed for the weeks of 6/20/2022 to 3/13/2023 (38 weeks). The CM stated that the laboratory was performing the necessary weekly maintenance but was not recording it on the maintenance log sheet. The CM confirmed in an interview on 6/29/2023 at 12:55 PM that the manufacturer required weekly maintenance on the Quant Studio 5/King Fisher Thermo analyzer was not documented for the weeks from 6/20/2022 to 3/13/2023 (38 weeks). The laboratory performs 1,170 Microbiology tests annually. .

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

. Based on procedure manual review and interview with the Clinical Manager (CM), the Laboratory Director (LD) failed to approve, sign, and date verification of a new test procedure's performance characteristics, including the precision and accuracy of the test and test system as evidenced by the following: The surveyor asked to review the validation for the one (1) new Quant Studio 5/King Fisher Thermo UTI PCR test (Urine for UTI and Antibiotic Resistance Testing/Rectal Swabs for Pathogens and Antibiotic Resistance Markers associated with UTI). The review revealed that the LD failed to review and approve the new procedure. The CM confirmed in an interview on 6/29/2023 at 12:40 PM that the LD failed to review and approve the validation for the UTI PCR test. The laboratory performs 1,170 Microbiology tests annually. .

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Clinical Manager (CM) on 6/29/2023, the Technical Supervisor failed to maintain documentation to verify the initial training of testing personnel as evidenced by the following: The surveyor asked to review the personnel and training records for the one (1) out of one (1) new Testing Person (TP). The review revealed that there was no documentation maintained to verify that the new TP received initial training when hired. The CM confirmed in an interview on 6/29/2023 at 12:45 PM that that no documentation was maintained to verify that the new TP received initial training when hired. The laboratory performs 1,170 Microbiology tests annually. .

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Clinical Manager (CM) on 6/29/2023, the Technical Supervisor (TS) failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for to review the personnel competency records. The review revealed that a semiannual competency evaluation was not performed and documented for the one (1) out of one (1) Testing Person (TP) performing high complexity PCR testing. The CM confirmed in an interview on 6/29/2023 at 12:45 PM that the TS failed to perform and document a semiannual competency evaluation for the one (1) out of one (1) TP in the first year of performing high complexity PCR testing. The laboratory performs 1,170 Microbiology tests annually. .

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Clinical Manager (CM) on 6/29/2023, the Technical Supervisor (TS) failed to evaluate and document the performance of individuals responsible for high 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 an annual competency evaluation was not performed and documented at least annually for the one (1) out of one (1) Testing Person (TP) performing high complexity PCR testing. The CM confirmed in an interview on 6/29/2023 at 12:45

PM that the TS failed to perform and document an annual competency evaluation for the one (1) out of one (1) TP in 2023 after the first year of performing high complexity PCR testing. The laboratory performs 1,170 Microbiology tests annually. .