

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0907996	(X3) Date Survey Completed 10/22/2024
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, PC laboratory on 10/22/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with testing person one (TP1) on 10/22/2024, the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials as evidenced by the following: The surveyor toured the PCR laboratory on 10/22/2024. The tour revealed the following: An eye wash station was observed. Upon request for maintenance and safety procedures it was revealed that no safety procedure was established for the proper use and maintenance of the eye wash. TP1 confirmed in an interview on 10/22/2024 at 1:35 PM that the laboratory did not have safety procedures established for the use and maintenance of the eye wash to ensure protection from hazards. .</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with testing person one (TP1) on 10/22/2024, 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. TP1 confirmed in an interview on 10/22/2024 at 11:25 AM 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. This is a repeat deficiency.