

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2117558	(X3) Date Survey Completed 07/16/2026
Name of Provider or Supplier Atlantic Men's Clinic Boca Raton, Llc	Street Address, City, State 2201 Nw Corporate Blvd Ste 100, Boca Raton, FL	
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	An announced CLIA recertification survey was conducted at Atlantic Men's Clinic Boca Raton LLC on July 16, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493.1421 Condition: Laboratory Testing Personnel
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have 2 of 5 Testing Personnel (B and F) qualified for Testosterone and Prostate-Specific Antigen (PSA) testing on the Fast Pack System (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50

weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have 2 of 5 Testing Personnel (B and F) qualified for Testosterone and Prostate-Specific Antigen (PSA) testing on the Fast Pack System. Findings Included: 1. Review of Personnel Records revealed Testing Personnel B and Testing Personnel F had translated foreign high school diplomas. Both translated high school diplomas did not state the diplomas met United States (US) high school standards. 2. Review of Testing personnel B's Personnel Evaluation Checklist revealed Testing Personnel B had performed Fast Pack testing from 3/31/2025 to 2/01/2026 with the Laboratory Director's signature. 3. Review of Testing Personnel F's Personnel Evaluation Checklist revealed Testing Personnel F had performed Fast Pack testing from 8/01/2023 -2/01/2025 with the Laboratory Director's signature. 4. On 7/16/2026 at 12:00 PM, Operations Manager A and Operations Manager B confirmed Testing Personnel B and Testing Personnel F had no foreign equivalences for US standards.