Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2117558	06/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic Men's Clinic Boca Raton, Llc	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	A recertification survey conducted on 6-18-2020, found that Atlantic Men's Clinic clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to create job responsibility policies for technical consulant (TC) and Clinical Consultant (CC) in the procedure manual. Findings Included: A review of the procedure manual revealed no job responsibility policies for TC and CC . During an interview on 6/18/2020 at 1: 52 pm, testing person A confirmed the procedure manual had no job responsibility policies for CC and TC.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to approve and sign testosterone (TSA) and prostate-specific antigen (PSA) instrumentation validations for 0373 and 0389 Qualigen Fast Pack IP System Instruments in 2019. Findings Include: A review of 0373 Qualigen Fast Pack IP System manual revealed that TSA and PSA validation for Fast Pack IP system instrument was not signed by LD in April and September 2019, as required. During an interview on 6-18-2020 at 1: 52pm, testing person A and laboratory director confirmed that 0373 and 0389 Qualigen Fast Pack IP system Instrument validations were not approved and signed by the LD.