Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2117557	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic Men's Clinic Plantation Llc	7901 Sw 6th Ct Ste 110, Plantation, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on instrument calibration record review for two- year record review period (year 2016 to 2018) and interview with the laboratory director, the laboratory failed to conduct and document the calibration verification, at least once every six months for Fastpack IP System Qualigen machines from November 2016 to August 2017. The findings include: Calibration record review on 7/26/18 at 2pm from two year review period (2016-2018) showed that the laboratory did not perform the calibration

	verification for Fastpack IP System Qualigen machines 0011 and 0079 from November 2016 until August 2017 and did not have the calibration verification records. On 7/26/18 at 3:00 PM, laboratory director confirmed that the laboratory did not perform the calibration verification for Fastpack IP System Qualigen machines 0011 and 0079 after October 2016 until August 2017 and did not have the calibration verification records.