Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2109322	01/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mens Wellness Centers	4050 Innslake Drive - Suite 360, Glen Allen, VA	

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 the Men's Wellness Centers on January 13, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a tour of the laboratory, review of the policy and procedures (P&P),

	calibration verification documentation, and an interview with the clinical operations manager, the laboratory failed to follow the manufacturer's six (6) month calibration verification instructions for Testosterone and Prostate Specific Antigen (PSA) analytes in calendar year 2018 and up to the date of the inspection on January 13, 2020. Findings include: 1. During a tour of the laboratory at approximately 1:10 PM, the inspector noted two (2) Qualigen FastPack analyzers in use for patient immunoassay PSA and Testosterone testing: Machine 1 (SN 0902), Machine 2 (SN 0802). 2. Review of P&P revealed the following statement by manufacturer: "At least once every six months, verify calibration of the FastPack System using FastPack Method Verification Kits to verify that the instrument is accurate to the limits of the reportable range specified by Qualigen." The laboratory director signed review and approval of the manufacturer operation guide on March 1, 2016. 3. Review of the Testosterone and PSA calibration verification records from June 1, 2018 up to the date of the inspection, revealed: Machine 1 (SN 0902) - PSA calibration verification performed 3/1/18 and 3/16/19; Machine 2 (SN 0802) - Testosterone calibration verification performed 3/1/18 and 3/16/19. The inspector requested to review additional calibration verification documentation as described by manufacturer instructions. The documentation was not available for review. 4. An exit interview with the clinical operations manager at approximately 4:00 PM confirmed the findings.