Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2098747	03/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Men's Wellness Centers, Llc	827 Diligence Drive - Suite 206, Newport News, 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 Men's Wellness Centers - Newport News that concluded on March 6, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, proficiency testing (PT) records, and interviews, the laboratory failed to follow their established policy to test PT testosterone specimens in the same manner as patients for one (1) of five (5) Chemistry PT events reviewed. Findings include: 1. Review of lab's PT policy revealed the statements: "Test PT samples in the same manner as you would patient samples." "Do not repeat PT sample testing unless you would repeat a patient test in the same situation." 2. Review of the laboratory's American Proficiency Institute (API) Chemistry proficiency testing records (account # 68580) for 2023 Events 2 and 3, and 2024 Events 1 - 3 (5 events in total) revealed both testosterone proficiency samples (IA-01 and IA-02) in 2024 Event 1 were tested twice on 1/22/24. Both PT sample results were within normal range and instrument printouts contained no flags or alerts. 3. In an interview on 1/13/25 at approximately 4:30 PM when asked when

	patient tests are repeated, the primary testing personnel (TP) stated that patient test reports are given to the doctor and the doctor decides if patient test needs repeating. 4. On 3/6/25 at approximately 10:10 AM, the primary testing personnel confirmed that the samples were ran twice, once on each Qualigen Fast Pack Instrument.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient test logs, and interview, the laboratory failed to follow their established schedule of performing two levels of external Testosterone and Prostate-specific Antigen (PSA) QC every 7 days during two (2) weeks out of the 17 months reviewed with sixty (60) patients resulted. Review timeframe: July 2023 through December 2024. Findings include: 1. The laboratory utilizes the Qualigen Fast Pack System to test patient Testosterone and PSA. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed that Qualigan QC is to be performed weekly (each Tuesday) prior to the 1st patient. 2. Review of the Qualigen QC records revealed Testosterone QC performed on Qualigen instrument #1 (Serial Number (SN) 0784), and PSA QC performed on Qualigen instrument #2 (SN 0373) on the 16th, 21st, and 28th of November 2023. No Testosterone and PSA QC was documented during the timeframe of November 1, 2023 to November 15, 2023. 3. Review of the November 2023 patient test logs revealed thirty three (33) patients tested for Testosterone and twenty seven (27) patients tested for PSA between November 1st and November 15th. (A total of 60 patients tested.) 4. In an exit interview on 3/6/25 at approximately 10:10 AM, the primary testing personnel confirmed there was no QC documented in the timeframe listed above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

	This STANDARD is not met as evidenced by: Based on a review of policies and procedures, quality control (QC) records, and interview, the laboratory failed to follow their established policy to review Endocrinology quality control statistics monthly during the seventeen (17) months reviewed. Review timeframe: July 2023 through December 2024. Findings include: 1. Review of the laboratory's policy for QC review revealed that the lab director (LD) is to review and sign QC Levy Jennings (LJ) plots monthly. 2. Review of the Endocrinology QC records revealed the following dates and LD signature of review for Testosterone and Prostate-Specific Antigen (PSA) QC LJ charts: July 2023 - December 2023 review dated 6/27/24, January 2024 - June 2024 review dated 6/27 /24, and July 2024 - December 2024 review dated 12/18/24. 3. In an interview on 1/13 /25 at approximately 4:30 PM, the primary testing personnel (TP) stated that the LD reviews QC when on-site and initials/signs twice a year. 4. During an exit interview on 3/6/25 at approximately 10:10 am with the primary TP, it was confirmed that the LD documented LJ review twice a year.