Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2098747	06/08/2023
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 initial survey was conducted at Men's Wellness Centers, LLC (Newport News) on June 6, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included follow up interviews with the laboratory director and technical consultant on 6/8/23. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), chemistry proficiency testing (PT) records, and an interview, the laboratory failed to document rotation of PT among all personnel performing patient Prostate Specific Antigen (PSA) and Testosterone testing in calendar years 2021, 2022, and up to the day of the inspection on June 6, 2023. Findings include: 1. Review of the CMS 209 laboratory personnel form revealed that the lab director identified five (5) laboratory testing performing (TP) responsible for patient PSA and Testosterone testing. 2. Review of the American Proficiency Institute (API) PT Core Chemistry modules in calendar year 2021 through 6/8/23 revealed that TP A signed attestations for performance of: API Core Chemistry 2021 (Events 1-3); API Core Chemistry 2022 (Events 1-3); API Core Chemistry 2023 Event 1; TP A performed/signed attestations for 7 of 7 events reviewed and outlined above. (See attached Testing Personnel Code Sheet) 3. An interview with the technical consultant on 6/6/23 at approximately 2:30 PM confirmed the above findings.

D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2020 proficiency testing (PT) records, lack of documentation, online PT vendor score reports, and interviews, the laboratory failed to retain documentation of a review/evaluation for three (3) of 3 core chemistry immunoassay PT modules for Prostate Specific Antigen (PSA) and Testosterone in calendar year 2020 while reporting one thousand six hundred (1,600) patient test results. Findings include: 1. Review of the laboratory's 2020 American Proficiency Institute (API) chemistry PT records (Events 1-3) revealed no retained scored results or documentation of a review/evaluation for: 2020 Endocrinology/Immunoassay Event 1: PSA challenge samples IA 01-02, Testosterone challenge samples IA 01-02 2020 Endocrinology/Immunoassay Event 2: PSA challenge samples IA 06-07, Testosterone challenge samples IA 06-07 2020 Endocrinology/Immunoassay Event 3: PSA challenge samples IA 11-12, Testosterone challenge samples IA 11-12 2. The inspector requested to review the API results and evaluation documentation for the 3 chemistry module events outlined above. No documentation of an evaluation was available for review. 3. A follow up review of PT results from the API vendor on 6/7 /23 revealed the following scores were reported: Chemistry Endocrinology Immunoassay: 2020 1st - PSA 100%, Testosterone 100% 2020 2nd - PSA 100%, Testosterone 50 % - API noted unsatisfactory performance for Testosterone 2020 3rd - PSA 100%, Testosterone 100% 4. Review of Qualigen Fast Pack moderate complexity patient test logs for calendar year 2020 revealed that the laboratory analyzed and reported one thousand (1,000) Testosterone and six hundred (600) PSA, a total of 1,600 results. 5. A follow up interview with the technical consultant and lab director on 6/8/23 at approximately 5:35 PM confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's user guide, procedures, equipment maintenance records, lack of documentation, and interviews, the laboratory failed to follow their annual calibration maintenance protocols for two (2) of 2 positive displacement sample pipettes utilized for Prostate Specific Antigen (PSA) and Testosterone patient testing during the review timeframe of August 2019 to the date of the inspection on June 6, 2023. Findings include: 1. During a laboratory tour on 6/6 /23 at approximately 11:00 AM, the inspector noted one Gilson Guest 100 microliter (ul) pipette, serial number (SN) JC05684, in use for Qualigen FastPack analyzer

	patient sample preparation for PSA and Testosterone testing. The inspector noted a Pipette.com calibration sticker dated 11/30/2022 with note: due for calibration on 11 /30/2023. The lead testing personnel stated at approximately 11:10 AM, "we also have a second pipette as our back up". The inspector noted that the second pipette, SN JD05679, had a Pipette.com calibration sticker dated 05/03/2023 with note: due for calibration on 05/03/2024. 2. Review of the Qualigen manufacturer's user guide revealed a policy, "Annual Recalibration of the Positive Displacement Sample Pipette" which outlined instructions for pipette calibrations. The policy stated "Proper performance of pipette is critical to obtain accurate results. The pipette included with the FastPack System is a costly piece of equipment that requires periodic recalibration which must be done by a factory certified dealer". 3. Review of the laboratory's procedure manual revealed a quality assurance "Quick Reference Task Log" that outlined Pipette Recalibration to be completed annually (QA Manual Tab 18-5). 4. Review of the laboratory's equipment maintenance records from August 2019 to the date of the survey on 6/6/23 revealed no additional pipette calibration documentation other than the Pipette.com stickers observed on the pipettes as outlined above. The inspector requested to review additional annual calibration records. The requested documentation was not available for review. 5. A follow up interview with the technical consultant and lab director on 6/8/23 at approximately 5:35 PM confirmed the above findings.