

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2100848	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier Men's Wellness Centers Llc	Street Address, City, State 996 First Colonial Road, Virginia Beach, 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, LLC (Virginia Beach) on September 20, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel files, and an interview, the laboratory failed to rotate two (2) of three (3) PT chemistry event challenges among testing personnel (TP) responsible for Prostate Specific Antigen (PSA) and Testosterone patient testing in calendar year 2022. Findings include: 1. Review of the 2022 American Proficiency Institute (API) Core Chemistry PT records (2022 Events 1-3) revealed that TP A signed the PT attestation as performing 2022 Event 2 and 3. TP A performed two (2) of three (3) events in calendar year 2022. **See Testing Personnel Code Sheet. 2. Review of the CMS 209 laboratory personnel form and personnel files revealed that the lab director identified five qualified TP who performed routine non-waived patient PSA and Testosterone testing during the timeframe of the events reviewed and outlined above. 3. An exit interview with the laboratory technical consultant on 9/20/23 at 3:30 PM on confirmed the above findings.</p>