

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2100848	(X3) Date Survey Completed 11/09/2021
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 November 9, 2021 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 and include the Condition under 42 CFR part 493 CLIA Regulation: D6033 -42 CFR. 493.1409 Technical Consultant-Moderate Complexity.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director and testing personnel for three (3) of five (5) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) chemistry PT documentation (2019 Event 3, 2020 Events 1-3, 2021 Special Self Evaluation 1) revealed no signed attestation statements for: 2020 Event 1, 2020 Event 2, 2021 Self Evaluation 1. The inspector requested to review the attestation documentation for the chemistry events listed above. No documentation was available for review. 2. An exit</p>

	<p>interview with the testing personnel and patient coordinator on 11/9/21 at approximately 12:30 PM confirmed the above findings.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, procedures, and an interview, the technical consultant failed to provide laboratory oversight as the laboratory failed to follow the approved Qualigen FastPack policy for personnel semi-annual and annual chemistry competency assessments during the twenty-seven months reviewed (August 2019 to the date of the survey on 11/9/21). Cross Reference: D6046 and D6053 (REPEAT DEFICIENCIES).</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>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), testing personnel (TP) records, procedures, and an interview, the technical consultant (TC) failed to perform annual competency evaluations for TP A in calendar years 2019 and 2020. (See Personnel Code Sheet.) *REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 form revealed that the laboratory director also performs the duties of TC and 6 personnel were identified as responsible for performing patient Prostate Specific Antigen (PSA) and Testosterone chemistry testing during the review timeframe of August 2019 to 11/9/21. 2. Review of the laboratory personnel files revealed TP A lacked documentation of an annual chemistry competency evaluation in calendar years 2019, 2020, and year to date 2021. The inspector requested to review the annual competency assessments. No records were available for review. 3. Review of the laboratory's Qualigen FastPack procedures revealed a Personnel Evaluations Checklist that stated: "Evaluate those individuals that operate the FastPack IP System after the first 6 months of testing, then yearly thereafter." 4. An exit interview with the testing personnel and patient coordinator on 11/9/21 at approximately 12:30 PM confirmed the above findings</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

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), testing personnel (TP) records, procedures, and an interview, the technical consultant (TC) failed to document performance of the semi-annual competency assessment for one (1) new laboratory staff member (TP B) in calendar year 2020. (See Personnel Code Sheet.) *REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 form revealed that the laboratory director also performs the duties of TC and 6 personnel were identified as responsible for performing patient Prostate Specific Antigen (PSA) and Testosterone testing. 2. Review of personnel records revealed that TP B was initially trained and started performing PSA/Testosterone chemistry testing in November 2019. The record review revealed no semi-annual competency assessment for TP B. The inspector requested to view the semi-annual competency assessment. No record was available. 3. Review of the laboratory's Qualigen FastPack procedures revealed a Personnel Evaluations Checklist that stated: "Evaluate those individuals that operate the FastPack IP System after the first 6 months of testing, then yearly thereafter." 4. An exit interview with the testing personnel and patient coordinator on 11/9/21 at approximately 12:30 PM confirmed the above findings.