Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2100848	07/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Men's Wellness Centers Llc	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 July 25, 2019 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:
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of procedures, calibration verification documentation, quality control (QC) records, manufacturer's user guide, Individualized Quality Control Plan (IQCP), patient test logs, and an interview, the laboratory failed to: 1. follow the manufacturer's six month calibration verification instructions for Testosterone and Prostate Specific Antigen (PSA) in calendar year 2018 and up to the date of the inspection on 7/25/19. Cross Reference D5439; **REPEAT DEFICIENCY. 2. provide documentation of a lab director approved IQCP (for discontinuance of daily QC/ implementing once weekly QC) with Risk Assessment for PSA and Testosterone testing from 7/5/18 to the date of the inspection while reporting five thousand one hundred fifteen patient results. Cross Reference D5445.
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, review of the laboratory's procedure manual, calibration verification documentation, and an interview, the laboratory failed to follow the manufacturer's six (6) month calibration verification instructions for Testosterone and Prostate Specific Antigen (PSA) in calendar year 2018 and up to the date of the inspection on 7/25/19. **REPEAT DEFICIENCY Findings include: 1. During a tour of the laboratory at approximately 10 AM, the inspector noted two (2) Qualigen FastPack analyzers in use for patient immunoassay PSA and Testosterone testing: Machine 1 (SN 0939) Machine 2 (SN 0530) 2. Review of the procedure manual revealed manufacturer's policy instructions to perform Qualigen FastPack chemistry analyzer calibration verification twice annually. The policy stated "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." 3. Review of the laboratory's Qualigen analyzer's Testosterone and PSA calibration verification records from August 2017 up to the date of the inspection, revealed: Machine 1 (SN 0939) - No PSA calibration verification records from January 2018 up to 7/25/19; Machine 2 (SN 0530) - No Testosterone calibration verification recorded in calendar year 2018. The inspector requested to review documentation of the calibration verification procedures outlined above. The documentation was not available for review. 4. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, manufacturer's user guide, the laboratory's Individualized Quality Control Plan (IQCP), patient test logs, and an interview, the laboratory failed to provide documentation of a lab director (LD) approved IQCP with Risk Assessment (RA) for Prostate Specific Antigen (PSA) and Testosterone testing from 7/5/18 to the date of the survey on 7/25/19 while reporting five thousand one hundred fifteen (5,115) patient results. Findings include: 1. Review of the laboratory's Qualigen FastPack PSA and Testosterone QC records from August 2017 to the date of the survey revealed a change in QC documentation from two (2) levels of QC per day of testing to 2 levels of QC once per week starting on 7/5/18 and up to 7/25/19. 2. Review of the Qualigen FastPack IP System 2 manufacturer's guide revealed a quality assurance protocol ("Steps to Complete for Patient Testing- How to Use the QA Log") which stated under topic "Before You Begin Testing Patients: Run QC before testing patient samples. Ensure that QC results are within the correct range before testing patient patients. Note- if your laboratory has implemented an approved IQCP option for QC and qualify to run weekly controls, run QC before testing patients once per week, on the same day." 3. The inspector requested to review the laboratory director's approved IQCP with RA documentation for the Qualigen analyzer completed prior to the implementation of the once weekly QC in July 2018. No records were available for review. The clinical operations manager stated at approximately 12:30 PM, "Our former lab director contacted the manufacturer and was informed we could go to once per week QC at all of our offices. I do not have the documentation of assessment checklists performed for the time that we switched to weekly but I have a checklist that was started in June 2019." 4. Review of the Qualigen patient test logs revealed the laboratory reported the following number of patient results from 7/5/18 to 7/25/19 without daily QC monitoring: Testosterone - two thousand eight hundred ninety-seven (2,897); PSA- two thousand two hundred eighteen (2,218); a total of 5,115 patient results. 5. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. 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), laboratory personnel files, and an interview, the technical consultant (TC) failed to assess annual Qualigen FastPack immunoassay competency assessments for two (2) of six (6) testing personnel in 2017 and 2018. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director also performed the duties of TC and that 6 testing personnel performed patient Qualigen FastPack Prostate Specific Antigen and Testosterone testing during the twenty-four months reviewed (review timeframe June 2017 to 07/25/19). 2. Review of the laboratory personnel files revealed no annual competency assessment documentation for: Testing Personnel B (TP B) in calendar years 2017 and 2018;

	Testing Personnel D (TP D) in 2018. (See Personnel Code Sheet.) The inspector requested to review the competency assessments outlined above for TP B and TP D. The records were not available for review. 3. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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. 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), personnel records, and an interview, the technical consultant (TC) failed to document performance of the semi-annual competency assessment for one (1) new laboratory testing personnel (TP C) in calendar year 2018. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performed the duties of TC. 2. Review of personnel records for TP C revealed documentation of initial training checklists for Qualigen FastPack immunoassay testing on 10/17/17. The inspector noted an annual competency assessment recorded in October 2018 for TP C. The inspector requested to view the semi-annual competency assessment documentation for TP C. No documentation was available for review. 3. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the laboratory director failed to retain documentation of personnel qualifications for one of six testing personnel performing Prostate Specific Antigen and Testosterone patient testing from May 2019 to the date of the inspection on July 25, 2019. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at

	least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and 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), personnel records, and an interview, the laboratory director (LD) failed to retain documentation of personnel qualifications for one (1) of six (6) testing personnel from May 2019 to the date of the survey on July 25, 2019. Findings include: 1. Review of the CMS 209 form revealed 6 testing personnel performed patient Prostate Specific Antigen (PSA) and Testosterone testing during the twenty-four (24) months of review. 2. Review of the laboratory's personnel records revealed no documentation of education for Testing Personnel A (TP A). TP A's initial Qualigen FastPack training and start of patient testing was documented on 05/07/19. The inspector requested to review TP A's education documentation. No records were available for review. (See Personnel Code Sheet.) 3. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.