Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2098747	07/23/2019
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, LLC (Newport News) on July 23, 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. 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 testing personnel for three (3) of five (5) immunoassay PT events in the review timeframe of June 2017 to July 2019. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) Prostate Specific Antigen (PSA) and Testosterone immunoassay PT documentation (2017 Event 1 and 2, 2018 Event 1 and 2, 2019 Event 1), a total of 5 events, revealed no testing personnel signed attestation statements for: 2017 Event 2 2018 Event 1 2018 Event 2 The inspector requested to review the attestation

	documentation for the 3 PSA and Testosterone PT events outlined above. No documentation was available for review. 2. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
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 performance verification records for the Qualigen FastPack IP System 2 analyzers, patient test logs, quality control records, manufacturer's user guide, the laboratory's Individualized Quality Control Plan (IQCP), immunoassay analyzer validation study, and an interview, the laboratory failed to: 1. document review or evaluation, by the laboratory director, of the accuracy, precision, and reportable range for Prostate Specific Antigen (PSA) testing prior to reporting three hundred thirty-eight patient results on a newly installed Qualigen instrument from March 20, 2019 to the date of the survey on July 23, 2019; Cross Reference D5421. 2. provide documentation of a lab director approved IQCP with Risk Assessment for PSA and Testosterone testing from 7/5/18 to the date of the survey on 7/23/19 prior to reporting two thousand two hundred seventy-one patient test results; Cross Reference D5445.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a tour, review of performance verification records for the Qualigen FastPack IP System 2 analyzers, patient test logs, and an interview, the laboratory director (LD) failed to document review/evaluate the accuracy, precision, and reportable range for Prostate Specific Antigen (PSA) testing prior to reporting three hundred thirty-eight (338) patient results on the newly installed instrument from March 20, 2019 to the date of the survey on July 23, 2019. 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 0784; for Testosterone) Machine 2 (SN 0321; for PSA) 2. Review of all analyzer performance verification documentation records revealed that the laboratory installed a new FastPack instrument (SN 0321) on 03/20/19. The validation documentation for

	SN 0321 revealed no LD evaluation or verification of PSA accuracy, precision, or reportable range. The inspector requested to review documentation that the LD verified the Qualigen FastPack validation studies prior to patient testing for the newly installed analzyer. No documentation was available. 3. Review of patient test logs revealed that the laboratory reported 338 patient PSA results from analyzer (SN 0321) from March 2019 to the date of the survey on 7/23/19. 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), immunoassay analyzer validation study, 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 7/23/19 prior to reporting two thousand two hundred seventy-one (2,271) patient test 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 daily QC (two levels per day of patient testing) was discontinued in July 2018. The inspector noted 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 7/23/19. 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 at this office. I may have one completed for one of our other locations but that would have been completed in 2019." 4. Review of all analyzer performance verification documentation records revealed that the laboratory installed a new FastPack instrument (SN 0321) on 03/20/19. The validation documentation for SN 0321 revealed no LD evaluation or verification of PSA and Testosterone accuracy, precision, or reportable range, or RA for an IQCP for once per week QC. The inspector requested to review documentation that the LD verified the

	Qualigen FastPack validation studies and reviewed an IQCP RA prior to patient testing on the newly installed analyzer. No documentation was available. 5. Review of the Qualigen FastPack patient test logs revealed the laboratory reported the following patient results from 7/5/18 and up to 7/23/19: Testosterone: one thousand one hundred fifty-seven (1,157); PSA- one thousand one hundred fourteen (1,114); a total of 2,271 patient results. 6. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a tour, review of instrument validation documents, patient test logs, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, procedures, laboratory personnel files, proficiency testing (PT) records, and an interview, the laboratory director failed to: 1. document review and evaluation of the accuracy, precision, and reportable range for Prostate Specific Antigen (PSA) testing prior to reporting three hundred thirty-eight patient results on a newly installed immunoassay instrument from March 20, 2019 to the date of the survey on July 23, 2019. Cross Reference D6013. 2. to ensure the quality assurance (QA) policy for personnel competency assessments was followed for two of five personnel in calendar years 2017 and 2018. Cross Reference D6014. 3. document review of the laboratory's performance of immunoassay PT challenges on four out of five events reviewed (review timeframe: June 2017 to July 2019). Cross Reference D6018.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a tour, review of performance verification records for the Qualigen FastPack IP System 2 analyzers, patient test logs, and an interview, the laboratory director (LD) failed to document review/evaluate the accuracy, precision, and reportable range for Prostate Specific Antigen (PSA) testing prior to reporting three hundred thirty-eight (338) patient results on a newly installed instrument from March 20, 2019 to the date of the survey on July 23, 2019. 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 0784; for Testosterone) Machine 2 (SN 0321; for PSA) 2. Review of all analyzer performance verification documentation records revealed that the laboratory installed a new

	FastPack instrument (SN 0321) on 03/20/19. The validation documentation for SN 0321 revealed no LD evaluation or verification of PSA accuracy, precision, or reportable range. The inspector requested to review documentation that the LD verified the Qualigen FastPack validation studies prior to patient testing for the newly installed analyzer. No documentation was available. 3. Review of patient test logs revealed that the laboratory reported 338 patient PSA results from analyzer (SN 0321) from March 2019 to the date of the survey on 7/23/19. 4. In an exit interview with the clinical operations manager at approximately 1:30 PM, the above findings were confirmed.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. 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), procedure manual, personnel documentation, and an interview, the laboratory director failed to ensure the quality assurance (QA) policy for personnel competency assessments was followed for two (2) of five (5) personnel in calendar years 2017 and 2018. Findings include: 1. Review of the CMS 209 form revealed 5 testing personnel performed patient Qualigen FastPack Prostate Specific Antigen (PSA) and Testosterone testing during the twenty-four (24) months reviewed (review timeframe June 2017 to 07/23/19). 2. Review of the laboratory's procedure manual revealed a Qualigen FastPack QA policy (titled "Steps to Complete for Patient Testing- How to Use this Quality Assurance Log"). The policy stated "annually, the lab director will evaluate the personnel who perform the testing using the Personnel Evaluation Checklist". The inspector noted that the procedure manual competency checklist outlined three (3) forms: an initial evaluation, semi-annual, and annual. 3. Review of the laboratory personnel files revealed: Testing Personnel B: No annual competency assessment documentation in calendar years 2017 and 2018. Testing Personnel C: Documentation of an initial training checklist for Qualigen FastPack immunoassay testing on 10/17/17. The inspector noted no semi-annual review was included in the file. The inspector requested to review the competency assessments outlined above for Testing Personnel B and C. 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.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

	identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) results and an interview, the laboratory director (LD) failed to document review of the laboratory's performance in immunoassay PT on four (4) out of the five (5) events reviewed (review timeframe: June 2017 to July 2019). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) immunoassay Prostate Specific Antigen (PSA) and Testosterone PT records revealed no LD review of results for the following 4 test events: 2017 Event 2 2018 Event 1 2018 Event 2 2019 Event 1 2. 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 one (1) of five (5) 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 5 testing personnel performed patient Qualigen FastPack Prostate Specific Antigen (PSA) and Testosterone testing during the twenty-four (24) months reviewed (review timeframe June 2017 to 07/23 /19). 2. Review of the laboratory personnel files revealed no annual competency assessments available for Testing Personnel B (TP B) in calendar years 2017 and 2018. (See Personnel Code Sheet) The inspector requested to review the competency assessments for TP B. 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 semiannual 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 semiannual 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 (1) of five (5) testing personnel performing Prostate Specific Antigen and Testosterone patient testing from May 2019 to the date of the inspection on July 23, 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 five (5) testing personnel from May 2019 to the date of the survey on July 23, 2019. Findings include: 1. Review of the CMS 209 form revealed five (5) 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.