Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2109322	04/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mens Wellness Centers	4050 Innslake Drive - Suite 360, Glen Allen, 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 the Men's Wellness Centers on 04/04/22 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and an interview, the testing personnel (TP) failed to sign three of three attestation statements reviewed for the year 2020. Findings include: 1. Review of the American Proficiency Institute (API) chemistry PT records for all three (3) events in 2020 revealed lack of TP signature(s) of the attestation statements for the following: 2020 Event 1, 2020 Event 2 and 2020 Event 3. 2. An exit interview with the testing personnel and patient coordinator on 04/04/22 at 1600 confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation and

	interview with the primary testing personnel, the lab failed to verify the accuracy of the prostate specific antigen (PSA) and testosterone (TESTS) analytes twice a year in 2021. Findings include: 1. The laboratory utilizes American Proficiency Institute (API) PT for verification of accuracy of the PSA and TESTS analytes, categorized as non-regulated analytes. 2. Review of the API PT records revealed the lab participated in a Self-Evaluation on 10/29/21. The inspector requested to review additional accuracy verification documents for the calendar year 2021. The documents were not available for review. 3. An exit interview with the testing personnel and patient coordinator on 04/04/22 at 1600 confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), proficiency testing (PT) records, testing personnel (TP) records, quality assurance (QA) check lists, lack of documentation, and an interview, the current QA procedure failed to identify and address analytic issues in the subspecialty of chemistry from 01/01/20 and up to 12/31 /21, twenty-four months. Findings include: 1. Review of P&P, proficiency testing (PT) records, and testing personnel records revealed the following analytic issues in the subspecialty of chemistry: - Lack of documentation by TP for all three attestatments in 2020 (Refer to D2009), - Lack of documentation of verification of accuracy twice annually in 2021 (Refer to D5217) and, - Lack of documentation of TP annual competency assessments in 2020 (Refer to D6064). 2. Review of the current P&P and quality assessment policy (signed by the LD on 02/01/2016) revealed the following statement: "The laboratory director oversees the implementation of this QA Assessment Plan and helps identify and correct problems as they occur. When problems are identified, adjustments to the QA plan are made and implemented. Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems." 3. The QA review revealed that the laboratory utilizes a quality assurance checklist that included the following statements: Write "Y" for Yes, "N" No or "NA" for not applicable to indicate the outcome of the assessed item. Items of assessment include but not limited: Notification of any situation that could affect the FastPack IP test performance; personnel competency assessment review; proficiency testing; required controls, calibration and maintenance performed; and QA monitoring reviewed." 4. Review of the QA checklists revealed TP and the lab director signed all 12 QA checklists in 2020. All 12 checklists for 2021 lacked documentation of review and signature by the lab director. There was no documentation of issues or problems identified on all 24 QA checklists. 5. An exit interview with the testing personnel and patient coordinator on 04/04/22 at 1600 confirmed the findings.
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 the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, Policy and Procedures (P&P), and an interview, the technical conusltant (TC) failed to perform and document the annual competency assessments for three of six TP in 2020. Findings include: 1. Review of the CMS-209 form revealed the lab director performs the duties of TC and there were a total of six TP performing patient testing 2020. 2. Review of the TP records revealed lack of documentation by the TC of an annual competency assessments for the following in 2020: TP A, TP B, and TP C. See attached TP code sheet. The inspector requested to review the annual competency assessments. No records were avaiable for review. 3. Review of the P&P revealed a Personal Evaluations Checklist that stated, "Evaluate those individuals that operate the FastPack IP System after first 6 months of testing, then yearly thereafter." 4. An exit interview with the testing personnel and patient coordinator on 04/04/22 at 1600 confirmed the findings.