Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2319065	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Fl Wellness, Llc	812 W Colonial Dr, Orlando, FL	

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 initial survey was conducted at FL Wellness LLC on 5/12/26 to 6 /02/26. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited:: D5400 493.1250 - Condition: Analytic Systems D6000 493.1403 - Condition: Moderate Complexity Laboratory Director
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 record review and interview, the laboratory failed to run external quality controls (QC) at least once per month for 11 (May 2025 - July 2025, September 2025 - April 2026) of 12 months (May 2025 - April 2026) per manufacturers requirements and their Individualized Quality Control Plan for Prostate Specific Antigen (PSA) and Testosterone testing from 5/30/25 to 5/12/26. (See D5445)
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to run external quality controls (QC) at least once per month for 11 (May 2025 - July 2025, September 2025 - April 2026) of 12 months (May 2025 - April 2026) per manufacturers requirements and their Individualized Quality Control Plan for Prostate Specific Antigen (PSA) and Testosterone testing from 5/30/25 to 5/12/26. Findings Included: 1. Review of the procedure titled QC Requirements for Frend revealed, the requirements for external QC indicated to use "external control solution, Level 1 and Level 2" and perform external QC "Monthly." 2. Review of the QC logs for PSA on analyzer #1 revealed, two levels of external quality controls were run on 4/29/25, 8/24/25, and 5/02/26. 3. Review of the QC logs for PSA on analyzer #2 revealed, two levels of external quality controls were run on 8/24/25, and 5/02/26. 4. Review of the QC logs for Testosterone on analyzer #1 revealed, two levels of external quality controls were run on 4/29/25, 8 /24/25, and 5/02/26. 5. Review of the QC logs for Testosterone on analyzer #2 revealed, two levels of external quality controls were run on 8/24/25, and 5/02/26. 6. Review of the procedure titled QC Requirements for Frend (signed and dated by the Laboratory Director on 4/20/25) revealed, the requirements for external QC are to run "external control solution, Level 1 and Level 2" and perform external QC "Monthly." 7. During an interview on 5/12/26 at 11:32 AM, the Testing Personnel A acknowledged they had not been running external controls every month as required.
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 record review, and interview, the Laboratory Director failed to ensure the laboratory run external quality controls (QC) at least once per month for 11 (May 2025 - July 2025, September 2025 - April 2026) of 12 months (May 2025 - April 2026) per manufacturers requirements and their Individualized Quality Control Plan for Prostate Specific Antigen (PSA) and Testosterone testing from 5/30/25 to 5/12/26. (See D6020)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by:

	Based on record review and interview, the Laboratory Director failed to ensure the laboratory run external quality controls (QC) at least once per month for 11 (May 2025 - July 2025, September 2025 - April 2026) of 12 months (May 2025 - April 2026) per manufacturers requirements and their Individualized Quality Control Plan for Prostate Specific Antigen (PSA) and Testosterone testing from 5/30/25 to 5/12/26. (See D5445)