Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2172743	04/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ultimate Medical Center & Spa, Llc	12700 Sw 128th St Ste 205, Miami, 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 initial survey conducted on 04/14/2021 found that the ULTIMATE MEDICAL CENTER & SPA, LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview with Office Manager, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) and failed to run 2 levels of controls each day of patient testing from 02/17/2021 to 04/05/2021 for Testosterone and Prostate Specific Antigen (PSA). Findings Include: -Review of the Manufacturer' Instructions (MI) for Fast Pack IP System revealed that "two control levels must be used. Qualigen recommends that users run controls whenever: Patients testing is performed* A calibration is performed Repair maintenance is performed Improper storage or handling of FastPacks is suspected. Questionable patient results are obtained" * Review the IQCP Guidelines implemented by CMS. Instructions for the IQCP included in the MI. -The laboratory performed the risk assessment but failed to complete the IQCP and have it signed by the laboratory director. -The laboratory tested 4 patients from 02/17/21 to 04/05/21, patient 1 (2/17/21), patient 2 (3/3/21), patient 3 (3/31/21) and patient 4 (4/5/21) for Testosterone and PSA. No

	documentation of controls used on the days of patient testing. During an interview on 04/14/2021 at 10:30 AM, the office manager confirmed that the laboratory did not ran controls on the same testing date of the samples of reference and failed to complete the IQCP.