Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2332934	04/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Beach Medical X1 Llc	401 N Mills Ave Ste A, 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 Beach Medical X1 LLC on April 27, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the refrigerator, and the room temperature and humidity from 12/04/2025 to 04/13/2026. Findings included: 1. Review of the Daily Environmental & QC (Quality Control) Log noted, "Take refrigerator and room temperature readings along with relative humidity readings daily." 2. Review of the laboratory's QC documents revealed, the refrigerator, and the room temperature and humidity were not recorded. 3. During an interview on 04/27/2026 at 11:05 AM, the Laboratory Director acknowledged the refrigerator, and the room temperature and humidity were not recorded.
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 daily Quality Controls (QC) on the day of testing for two (Patient #3 and #4) of four (Patient #1 - #4) patients tested from 12/04/2025 to 04/13/2026. Findings included: 1. Review of the procedure titled, Using this Log noted, QC should be run daily and "Run QC before testing patients." 2. Review of the procedure titled, Individualized Quality Control Plan(IQCP) noted, "CLIA (Clinical Laboratory Improvements Amendments) requires a minimum QC frequency of two levels of controls each day of patient testing." 3. Review of the QC instrument printout revealed there were no instrument printouts documenting the controls were run on 04/13/2026. 4. Review of the patient reports for 04/13/2026 revealed, two patient testosterone results were reported out. 5. During an interview on 04/27/2026 at 11:05, the Laboratory Director acknowledged the calibration was performed on 04/13/2026, but did not see any documentation of the daily QC being run.