

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2293210	(X3) Date Survey Completed 09/13/2024
Name of Provider or Supplier Pur-Form	Street Address, City, State 3600 Fau Blvd Suite 101, Boca Raton, 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 certification survey was conducted from September 5, 2024 to September 13, 2024. Pur-Form clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of procedure manual, and interview, the laboratory failed to record the temperature and humidity of the laboratory and the temperature of the refrigerator where the Qualigen FastPack cartridges and the controls for PSA (Prostate-Specific Antigen) and Testosterone were stored from 05/10/2024 to 09/05/2024. Findings: On 09/05/2024 at 10:50 AM, the boxes for FastPack cartridges and the controls for PSA and Testosterone listed the storage temperature of 2 - 8 degrees Celsius (C) or 35 - 46 degrees Fahrenheit (F). Review of the FastPack IP System Procedure Manual noted "Ambient Operating Temperature: 15 degrees C (59 degrees F) to 32 degrees C (90 degrees F)" and "Operating Humidity: 10% to 80% relative humidity." On 09/05/2024 at 10:50 AM, the Project Manager acknowledged the temperature and humidity of the laboratory and the temperature of the refrigerator were not recorded.</p>