

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0909200	(X3) Date Survey Completed 12/10/2019
Name of Provider or Supplier Jeffrey Marcus Md Mph Pa	Street Address, City, State 7301 W Palmetto Park Rd Ste 108a, 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	A recertification survey conducted on 12/10/2019 found Jeffrey Marcus MD MMPH PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for 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 cryostat manual review and staff interview, the laboratory failed to document room temperature and humidity requirement to ensure optimal operation for the Leica CM 150 cryostat for 2 out of 2 years reviewed. The findings include: A review of Leica CM 150 manual revealed a requirement for optimal operation, a range of room temperature below 22 C and Humidity must not exceed 60 %. A review of temperature logs for 2018 and 2019, revealed no documentation of room humidity and temperature. During an interview on 1:30 pm at 12/10/19, office manager confirmed that there was no documentation of the room temperature and humidity for the period of reference.</p>