

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0957961	(X3) Date Survey Completed 03/08/2019
Name of Provider or Supplier Edward A Gross Md Pa D/B/A	Street Address, City, State 333 Arthur Godfrey Rd Ste 302, Miami Beach, 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
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 record review and interview with the laboratory director, the laboratory failed to document the room temperature and humidity for 2 out of 2 years reviewed. Findings include: Review of the cryostat manual Leica CM1510S indicated a requirement for room temperature no more than 35 C and humidity not above 60 %. Quality control records of histopathology room revealed that: there was no documentation of the humidity and room temperature during 2017 and 2018. During an interview on 03/08/19 at 2:00 p.m., the laboratory director confirmed that there was no record of room temperature or humidity for the years of reference.</p>