

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1085398	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Susana Leal Khouri Md Pa	Street Address, City, State 103400 Overseas Hwy, Suite 237, Key Largo, 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 testing person, the laboratory failed to document the room humidity during 2016, 2017 and 2018. Findings include: Review of the cryostat manual Leica CM1510S indicated a requirement for room humidity not above 60 %. Quality control records of histopathology room revealed that no documentation of humidity done during 2016, 2017 and 2018. During an interview on 06/21/18 at 10:30 a.m., the testing person confirmed that there was no record of room humidity for the period of reference.</p>