

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1012626	(X3) Date Survey Completed 11/13/2018
Name of Provider or Supplier Fort Myers Dermatopathology Pa	Street Address, City, State 12580 University Dr Ste 200, Fort Myers, 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 Manager the laboratory failed to document the humidity of the laboratory for 2 out 2 years (2017-2018) reviewed. Findings Included: Review of manufactures instructions for the automated slide stainer revealed that the humidity should not be greater than 80%. There was no documentation of humidity provided. During an interview on 11/13/18 at 1:00 PM the Laboratory Manager confirmed that the humidity had not been documented.</p>