

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1012567	(X3) Date Survey Completed 10/22/2018
Name of Provider or Supplier Florida Skin Cancer & Dermatology Specialists Pa	Street Address, City, State 3700 Nw 83rd St, Gainesville, 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 Office Manager, the laboratory failed to document room temperature and humidity in the laboratory for 2 (2016-2018) out of 2 years reviewed. Findings Included: Review of temperature logs revealed no temperature logs from 2016-2018. Review of manufacturers instruction revealed that the cryostat should be maintained at 18-35 degrees Celsius and humidity less than 60%. During an interview on 10/22/18 at 1:05 PM the Office Manager confirmed that room temperature and humidity were not being recorded.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the Technical</p>

Consultant (who is also the Laboratory Director) failed to perform a 6 month competency on 1 (#E) out of 1 newly hired Testing Person. Findings Included: Review of employee files revealed that Testing Person #E revealed a started full time in September 2017. A competency evaluation was conducted 09/17. A 6 month competency was conducted 6 months after patient testing began. During an interview on 10/22/18 at 12:30 PM the Office Manager confirmed that a 6 month competency evaluation had not been completed for Testing Person #E.