

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2089226	(X3) Date Survey Completed 05/31/2018
Name of Provider or Supplier Aqua Dermatology Of Florida Pa	Street Address, City, State 2481 Bobcat Village Center Rd Suite 101, North Port, 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 record the room temperature, room humidity, and cryostat temperature every day that testing was performed for 3 days (05/31/17, 10/04/17, 10/18/17) out of 4 months (November 16, May 17, October 17, March 18) reviewed. Findings Included: Review of policies and procedures revealed that the laboratory should record the room temperature, room humidity, and cryostat temperature every day that testing is performed. There was no room temperature, room humidity, and cryostat temperature recorded on 05/31/17, 10/04/17, and 10/18/17. Review of the patient accession log revealed that patients were tested on those 3 days. During an interview on 05/31/18 at 11:00 AM the Laboratory Manager confirmed that the temperatures were not recorded for the aforementioned days and that patients were tested.</p>