

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1091593	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Coastal Skin Surgery And Dermatology	Street Address, City, State 12469 Emerald Coast Pkwy Ste 101, Miramar 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, it was determined that the laboratory did not document room temperature and humidity requirements to assure optimal operating conditions and temperatures of the Cryostat Histopath QS 11 equipment each day of patient testing in accordance with CLIA requirements for the whole time that the laboratory was set up. Findings included: Review of the equipment's manufacturer procedure indicated that the AVANTI K QS 11 Cryostat requires an operating condition of 5 degrees centigrade to 35 degrees centigrade at a maximum relative humidity of 60 %. There was no room temperature and humidity log available for documenting the temperature of the laboratory room from May 2016 to 2018. Interview on 5/9/18 at 11:30 AM, testing person # 2 confirmed that the temperature and humidity of the laboratory room were not checked and documented daily since the time the laboratory had operated.</p>