

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2057914	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Southeastern Dermatology Group Pa	Street Address, City, State 12907 Panama City Beach Pkwy, Panama City 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
D0000	A recertification survey was conducted on September 5, 2018. Southeastern Dermatology Group PA had one deficiency found at the time of the visit.
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 monitor the cryostat temperature requirements to assure optimal operation several days from December 2017 and January to May 2018. Review of the laboratory procedures indicated that the cryostat (Avantik QS 11) operates at a freezing temperature of -20 to -30 degrees Celsius. The temperature log for December 2017 (12/14 and 12/20) and January to May 2018 (1/10, 1/31, 2/14, 2/21, 2/28, 3/14, 5/2, 5/23, 5/25 and 5/30) had the cryostat exceeded the normal range from -31 degrees Celsius to -33 degrees Celsius. There were no corrective actions available for documenting the cryostat which showed out of range temperatures. Interview on 9/5/18 at 10:00 AM , testing person # 2 confirmed that the temperatures of the cryostat which were trending to exceed the normal range for 2017 and 2018 had not been documented to perform corrective actions.</p>