

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2116895	(X3) Date Survey Completed 03/18/2020
Name of Provider or Supplier Sun Dermatology	Street Address, City, State 643 N Highway 231, Panama City, 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	An announced CLIA recertification survey was conducted at Sun Dermatology on March 18, 2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 laboratory staff, the laboratory failed to document humidity for 2 of 2 (2018 - 2020) years reviewed. Findings Included: Review of temperature logs revealed no humidity documented from March 2018 through March 2020. During an interview on March 18, 2020 at 11:00 AM, the laboratory supervisor confirmed that the humidity was not documented and the laboratory was not aware of the requirement to check the humidity daily.</p>