

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1056686	(X3) Date Survey Completed 06/11/2020
Name of Provider or Supplier Associates In Dermatology Inc	Street Address, City, State 3106 17th St, Saint Cloud, 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 June 11, 2020. Associates in Dermatology Inc. clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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, the laboratory failed to record the humidity of the room where testing was performed from 6/11/18 to 6/11/20. Findings: Review of the operations manual for the laboratory's Shandon Cryotome E cryostat noted that the maximum relative humidity should be 80%. A review of the laboratory's logs showed that the laboratory failed to record the humidity of the room where testing was performed. During an interview on 6/11/20 at 10:19 AM, the Operations Manager stated they did not record the humidity of the laboratory.</p>