

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0985646	(X3) Date Survey Completed 10/31/2018
Name of Provider or Supplier Associates In Dermatology Inc	Street Address, City, State 2205 North Blvd W, Davenport, 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 review of maintenance records, the cryostat instrument manual, and interview with the Operations Manager, the laboratory failed to document humidity for two out of two years (2016-2018). Findings Included: 1. Review of maintenance records revealed that per cent humidity was not documented for two out of two years (2016-2018) 2. Review of the cryostat instrument manual stated that the per cent humidity should be less than 80%. 3. Interview on 10/31/2018 at 1:30 PM with the Operations Manager confirmed that the per cent humidity was not recorded.</p>