

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1077405	(X3) Date Survey Completed 04/18/2019
Name of Provider or Supplier Winter Haven Dermatology Pa	Street Address, City, State 560 Ave K Se, Winter Haven, 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 Winter Haven Dermatology on 04/18/19. 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 the Office Manager the laboratory failed to record the humidity in the laboratory for 2 out of 2 (04/17-04/19) years reviewed. Findings Included: Review of manufacturer's instructions for the cryostat revealed that the laboratory must not have a humidity greater than 60%. Review of the laboratory logs revealed that the humidity was not recorded. Interview with the Office Manager on 04/18/19 at 10:11 AM confirmed that the laboratory did not record the humidity of the room where the cryostat was used.</p>