

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2037564	<b>(X3) Date Survey Completed</b>  09/25/2019
<b>Name of Provider or Supplier</b>  Skin And Cancer Associates Llp	<b>Street Address, City, State</b>  1447 Medical Park Blvd Ste 107, Wellington, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced recertification survey was conducted on 9/25/19 at Skin & Cancer Associates, LLP. Skin & Cancer Associates, LLP is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
<b>D5413</b>	<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 personnel, the laboratory did not document humidity in the room that the cryostat was used. The findings included: Review of quality control records for 2018 and 2019 on 9/25/19 revealed that room humidity was only documented in January, February, and June of 2018. The operator's manual for the cryostat specified that the instrument needed to be operating in no more that 60% humidity. During an interview with the Risk Manager at 10:39 a.m., on 9/25/19, he acknowledged that the histotechnician had not been documenting the room humidity.</p>