

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2043829	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Florida Center For Dermatology Laboratory	Street Address, City, State 1301 Plantation Island Dr South Ste 106b, Saint Augustine, 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	At the time of the announced, onsite recertification survey, Florida Center for Dermatology was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 staff interview, the laboratory failed to document the humidity of the laboratory for two of two years reviewed (2018-2019), and failed to ensure the required cryostat temperature on the "Cryostat Maintenance Policy" matched what was documented on the Cryostat Temperature Log for two of two years reviewed (2018-2019). Findings include: 1. Review of the temperature/humidity logs for 2018 and 2019 showed the room temperature was documented but the humidity was not. During an interview on 2/13/20 at 10:50am with the MOHs technician, it was confirmed that only room temperature was documented and not humidity. 2. The policy titled "Cryostat Maintenance Policy" states "The cryostats should be maintained at -21C to no colder than -26C for best sectioning". The cryostat temperature logs for 2018-2019 show an acceptable temperature range is -20C to -30 C. The average temperature range documented each day of testing is -28C to -30C which is out of range of the policy. The interview with the MOHs technician on 2/13</p>

/30 at 10:50am confirmed the temperature range for the cryostats in the laboratory is around -28C to -30C and the policy was incorrect.