

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2073813	(X3) Date Survey Completed 04/18/2018
Name of Provider or Supplier Z-Roc Dermatology Llc	Street Address, City, State 2838 E Oakland Park Blvd Ste 201, Fort Lauderdale, 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 record review and interview with the histology technician, the laboratory failed to document the room temperature and humidity in the room where the cryostat is during 2016, 2017 and 2018. The laboratory failed to document the cryostat temperatures for 4 out 16 days in May 2017. Findings include: 1-Review of the cryostat installation requirements revealed that there is a requirement for room temperature range 18-35 C and for humidity no more than 60 %. Review of temperature logs revealed that there was no documentation of room temperature nor humidity in 2016, 2017, and 2018. 2- Review of cryostat maintenance sheet revealed that there is a requirement to record the cryostat temperature every day of use. They used cryostat 16 days in May 2017 (1,2,4,5,8,9,11,12,15,16,17,18,22,25,26 and 30), there was no documentation of cryostat temperatures record in May (22, 25, 26 and 30) 3-During an interview on 04/18/18 at 11:00 a.m., the histology technician confirmed that there was no documentation of room temperature nor humidity during 2016, 2017, and 2018 for the cryostat room also confirmed that there was no documentation of cryostat temperature for the days cited above.</p>