

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0712932	(X3) Date Survey Completed 05/24/2019
Name of Provider or Supplier Parks Dermatology Center Llc	Street Address, City, State 400 Lakebridge Plaza Dr, Ormond Beach, 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 staff interview, the facility failed to document the temperature of the Cryostat instrument used to cut tissue for Histopathology testing for eight of eight testing days reviewed in December 2018. Findings included: The record review of the "Cryostat Temperature Log" for 2018 shows that no temperature was documented on December 4th, 5th, 6th, 10th, 11th, 12th, 18th, and 19th. The record review of the MOHs patient testing log showed 10 patients tested on the 4th, 9 patients on the 5th, 9 patients on the 6th, 10 patients on the 10th, 10 patients on the 11th, 10 patients on the 12th, 12 patients on the 18th, and 10 patients on the 19th. Interview with the clinic manager on 5/24/19 at 9:30AM confirmed that no temperature was documented for the month of December.</p>