

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D2131870	(X3) Date Survey Completed 02/26/2018
Name of Provider or Supplier Integrated Dermatology Of I Street	Street Address, City, State 900 17th Street Suite 300, Washington, DC	
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 the review of the laboratory's policies and procedures and the manufacturer's instructions, and interview with the Mohs Technician on February 26, 2017 at approximately 3:30 PM, the laboratory failed to develop environmental monitoring mechanism to ensure that the two (2) equipment used with Mohs procedure were stored and operated in accordance with the manufacturer's specifications (cryostat and microscope). The findings included: 1. Review of the Leica's (manufacturer of the cryostat) instructions for storage and operation of the cryostat revealed that the cryostat must be operated consistently, between 18-35 degrees centigrade (C). The storage of the cryostat must be between 5-50C. It should be noted that the cryostat is operated and stored in different rooms. Review of the laboratory's procedure manual did not reveal instructions to monitor the room temperature where the cryostat is stored or operated. 2. Review of the Leica's (manufacturer cryostat) instructions for storage and operation revealed that the maximum non-condensing relative humidity to be 60%. Review of the laboratory's procedure manual did not reveal instructions to monitor the relative humidity where the cryostat is stored or operated. 3. Review of the Leica's (manufacturer of the microscope) instructions revealed that the operating temperature to be between 10-40C and the storage temperature to be between -20-52 C. It should be further noted that the microscope is operated and stored in different</p>

rooms. Review of the laboratory's procedure manual did not reveal instructions to monitor the room temperature where the microscope is stored or operated. 4. Interview with staff confirmed the lack of monitoring mechanism for the room temperature and the relative humidity where the cryostat and the microscope are stored and operated.