

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2087783	(X3) Date Survey Completed 10/30/2018
Name of Provider or Supplier Pa Dermatology Partners Ne Phlly	Street Address, City, State 9501 Roosevelt Blvd Suite 508, Philadelphia, PA	
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 observation, review of manufacturer's instructions, and personnel interview of the Histotechnologist and Mohs Technologist on the date of the survey (10/30/2018), the Laboratory failed to follow manufacturer's instructions for storage of AcuDTM media, from 04/24/2017 through 10/30/2018. Findings include: 1. AcuDTM media is to be stored at 36 - 46 Fahrenheit (F) according to the manufacturer's instructions. 2. At the time of the survey (10:00 10/30/2018) the laboratory failed to document temperature of the refrigerator used for media. 3. The refrigerator used for media had 2 lots of AcuDTM media: Lot D 1255-117 (4 vials) Expiration date 19/11/28 Lot DR 90-0918 (96 vials) Expiration date 20/09/04 4. During the survey the Histotechnologist confirmed the above findings.</p>