

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1071476	(X3) Date Survey Completed 05/21/2019
Name of Provider or Supplier Vanguard Dermatology	Street Address, City, State 110-45 Queens Blvd, Suite 116, Forest Hills, NY	
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 a lack of humidity records and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's instructions to monitor and document the humidity. Findings Include: The Moh's processor confirmed on May 21, 2019, at approximately 11:30 AM that the laboratory failed to follow the directions of the Leica instrument manual to monitor and document the humidity of the room where Moh's processing occurs from June 2017 through the date of this survey.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observation of the reagents used for Moh's slide staining, and an interview with the Moh's processor, the laboratory failed to discontinue the use of the</p>

expired histological reagent. Findings Include: It was confirmed with the Moh's processor on May 21, 2019, at approximately 11:30 AM, the laboratory failed to discard the expired reagent Hemotoxylin, Lot # 17030416, which expired 2/6/ 2019. There were 149 patient specimens tested and results released during that time.