

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1088553	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier New York Cosmetic Skin & Laser Surgery Center	Street Address, City, State 121 East 60th Street - Suite 8ab, New York, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory policies/procedures, annual competency records and an interview with the Moh's technician, the laboratory failed to have a complete policy and procedure for personnel competency. Finding Include: It was confirmed by the Moh's technician on June 7, 2018, at approximately 1:00 pm that the laboratory failed to have a complete written procedure for annual competency to include direct observation of routine patient test performance which is one of six required components to assess the testing personnel's competency annually.</p>
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 an and interview with the Moh's technician, the</p>

laboratory failed to follow the manufacturer's instructions to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the Moh's technician, on June 7, 2018, approximately 12:30 pm that the Moh's technician failed to follow the manufacturer's written criteria to monitor and document the humidity of the room where Moh's testing is performed from June 16, 2016 through the date of this survey.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's records and an interview with the Moh's technician, the laboratory director failed to ensure that the annual competency review included direct observation and the laboratory followed the manufacturer's instruction to monitor and document the humidity of the room where testing is performed. Refer to D5209 and D5413