

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2032764	<b>(X3) Date Survey Completed</b>  03/13/2018
<b>Name of Provider or Supplier</b>  Michael Paltiel Md Pc	<b>Street Address, City, State</b>  64-05 Yellowstone Blvd, Cfu 101, Forest Hills, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 owner of the physician office laboratory (POL), the laboratory failed to have a complete policy and procedure for personnel competency. Finding Include: It was confirmed by the owner of the POL on March 13, 2018, at approximately 11:30 am 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>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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:</p>

Based on a lack of humidity records and a phone interview with the laboratory testing person, the 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 laboratory testing person via phone, on March 13, 2018, approximately 11:45 am that the testing person failed to follow the manufacturer's written criteria to monitor and document the humidity of the room where Moh's testing is performed for January 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 testing person via telephone, the laboratory director failed to ensure that the annual competency review included direct observation and that the laboratory follow the manufacturer's instruction to monitor and document the humidity of the room where testing is performed. Refer to D5209 and D5413