

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0129428	<b>(X3) Date Survey Completed</b> 11/21/2019
<b>Name of Provider or Supplier</b> Michael J Albom Md Pc	<b>Street Address, City, State</b> 33 East 70th Street, New York, 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>D5413</b>	<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 for the Leica cryostat to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the Moh's processor on November 21, 2019, approximately 11:30 AM that the laboratory has not followed the manufacturer's direction to monitor and document the humidity of the room where Moh's testing is performed.</p>
<b>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of QA procedures and an interview with the Moh's processor, the</p>

director failed to ensure that the laboratory's QA program for histopathology testing was maintained for all phases of laboratory testing. Refer to D5413