

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2091135	<b>(X3) Date Survey Completed</b>  10/25/2018
<b>Name of Provider or Supplier</b>  Anetta Reszko Md Pc	<b>Street Address, City, State</b>  1112 Park Avenue, Suite 1a, 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 to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the Moh's processor, on October 25, 2018, approximately 10:50 pm that the Moh's processor failed to follow the manufacturer's written criteria to monitor and document the humidity of the room where Moh's testing is performed from January 2, 2018 through the date of this survey.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the laboratory's quality assessment (QA) procedure and an interview with the Moh's processor, the laboratory failed to follow their procedure to perform QA reviews. Findings Include: It was confirmed by the Moh's processor on October 25, 2018 at approximately 11:25 am that the laboratory failed to perform their QA review since the date of the last survey performed on November 22, 2016.

**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, QA procedure and an interview with the Moh's processor, the laboratory director failed to ensure that 1) the manufacturer's instruction to monitor and document the humidity of the room where Moh's processing is performed and 2) Perform the laboratory's QA reviews. Refer to D5413 and D5791