

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2134036	<b>(X3) Date Survey Completed</b>  07/30/2018
<b>Name of Provider or Supplier</b>  Advanced Dermatology Pc	<b>Street Address, City, State</b>  37-51 82nd Street, Jackson Heights, 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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of records, surveyor's observation, and an interview with the office manager, the laboratory began patient specimen testing for Moh's surgery and fungal cultures on March 8, 2018 and failed to validate the cryostat and fungal culture media. Findings Include: It was confirmed with the office manager on July 20, 2018 at approximately 12:45 pm that the laboratory failed to validate the Leica cryostat instrument and dermatophyte testing media (DTM) prior to beginning patient testing.</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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:</p>

Based on a lack of records, and an interview with the office manager, the laboratory director failed to ensure that the QA program for histology and mycology testing was maintained to ensure quality laboratory services. Refer to: D5421