

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D1008584	<b>(X3) Date Survey Completed</b> 06/24/2022
<b>Name of Provider or Supplier</b> Advanced Dermatology Pc	<b>Street Address, City, State</b> 510 Montauk Highway, Suite A, West Islip, 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 the lack of training and competency documentation of fungal culture testing person, the laboratory failed to perform training and competency. Confirmed on an interview with general supervisor on 6/24/2022 about 11am.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy, the laboratory failed to establish frequency of QA policy and perform QA review. FINDINGS: 1. 2020 and 2021 annual QA review documentation was not available for review. 2. 2020 and 2021 annual QA review not performed confirmed with an interview with general supervisor on 6/24/3022 about 11:30am.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a lack of the training/competency documentation and annual QA documentation, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D5209 and D5291