

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1001930	(X3) Date Survey Completed 12/12/2024
Name of Provider or Supplier Advanced Dermatology Pc	Street Address, City, State 4 Technology Drive, Suite 180, East Setauket, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of personnel competency records, current Standard Operating Procedures (SOPs), as well as interview with the Office Manager (OM), the laboratory failed to draft, approve policies and procedures for Testing Personnel (TP) competency requirements. FINDINGS: 1. The current, approved SOPs did not include instructions for TP fungal culture competency assessment. 2. The OM confirmed the findings on December 12, 2024, at approximately 12:00 P.M.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs as well as interview with the OM, the Laboratory Director (LD) failed to document procedure approval and date of approval. FINDINGS: 1. The OM confirmed on December 12, 2024, at approximately 11:00 A.M. that the current, approved SOPs did not include documented LD approval and date of approval.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 review of Quality Assurance (QA) records as well as interview with the OM, the LD failed to perform and maintain annual QA review to assure quality of laboratory services provided. FINDINGS: 1. There was no documentation of annual QA review for 2022 and 2023. 2. The OM confirmed the findings on December 12, 2024, at approximately 12:30 P.M.