

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2133726	<b>(X3) Date Survey Completed</b>  09/12/2019
<b>Name of Provider or Supplier</b>  Advanced Dermatology Pc	<b>Street Address, City, State</b>  2580 Sunrise Highway, Bellmore, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor review of the twice per year verification records and an interview with the office manager, the laboratory failed to verify the accuracy of fungal cultures at least twice per year for calendar year 2018. Findings include: 1. On September 12, 2019 at approximately 10:00 AM the office manager confirmed surveyor's finding that the accuracy of fungal culture testing was verified once on 11/29/18. The laboratory's twice a year verification policy states: "Two times yearly 5 specimens are sent to another CLIA approved lab for verification". No other record of verification was available for review. 2. Approximately 70 patients' samples were tested and reported for fungal cultures in calendar year 2018.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or</p>

control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a surveyor review of the Mohs laboratory's procedure manual, Fungal culture procedure manual and interview with the office manager, the laboratory failed to have a complete and accurate written procedure manual to include the following: 1. A written policy for retention of Mohs slides and records; 2. The Fungal culture procedure manual still lists the former laboratory director as the current laboratory director. The laboratory must have an accurate and up to date procedure manual.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of competency assessment records and confirmed in an interview with the office manager, the laboratory director, acting as the technical consultant, failed to ensure that competency assessment for the histotechnician was performed in calendar year 2018.