

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1008584	(X3) Date Survey Completed 10/12/2018
Name of Provider or Supplier Advanced Dermatology Pc	Street Address, City, State 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.		

(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 surveyor's review of laboratory records and an interview with the practice manager, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components that assess testing personnel's competency, twice annually during the first year of testing and annually thereafter. The six required components are: 1. direct observation of routine patient test performance, including preparation, specimen handling and testing; 2. monitoring the recording and reporting of test results; 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.</p>
D5403	<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.</p>

(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 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 surveyor review of records for mycology, histopathology and an interview with the practice manager at the time of this survey, the laboratory failed to have a complete written procedure manual to include the following procedures: 1. Patient preparation, specimen collection, labeling of the specimen to include patient's name and unique identifier and when appropriate specimen source, storage/temperature and preservation, and criteria for specimen acceptability and rejection for DTM; 2. Quality control procedures for DTM; 3. Verification accuracy at least twice annually for mycology testing; 4. Policy for retention and storage of histopathology slides and records.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on a review of temperature records and an interview with the practice manager, the laboratory failed to follow the manufacturer's instructions for monitoring and maintaining room and the refrigerator temperatures on each day of testing in calendar year 2017 and up to survey date. Findings Include: 1. The practice manager confirmed on the day of the survey at approximately 1:00 PM that the laboratory monitored the room temperature used to incubate the fungal cultures once per week and not on each day the lab is open as the manufacturer's instruction for incubation of the fungal cultures. 2. The practice manager confirmed that the laboratory monitored the refrigerator temperature used to store boxes of DTM once per week and not on each day the lab is open.