

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0915461	(X3) Date Survey Completed 07/25/2023
Name of Provider or Supplier Advanced Dermatology Pc	Street Address, City, State 145 W 86th Street Suite 1a, New York, 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 the lack of training records and an interview with office manager, the laboratory director failed to follow the established competency evaluation policy regarding the training, six-month, and annual performance evaluations of the six new Clinical Medical Assistant (CMA) personnel. FINDINGS: 1. No documentation of training, six-month, and annual competency evaluations for the six new CMAs who performed Acuderm DTM media quality control utilized in fungal culture testing. 2. The office manager confirmed on July 25, 2023, at 10:30 A.M. that the laboratory director did not perform and document the required training and six-month competency evaluations for the six new CMAs hired in the calendar year 2022. Refer to D6029.</p>
D5217	<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 the review of the twice year verification procedure, lack of verification records, and an interview with the office manager, the laboratory failed to perform twice year fungal culture testing verification of the four fungal culture testing</p>

providers for the calendar years 2020, 2021, 2022, and 2023. FINDINGS: 1. The verification procedure indicated, " ...that the laboratory will perform twice yearly verification using five samples in the months of December and July with either each provider and/or another Advanced Dermatology office." 2. The office manager confirmed on July 25, 2023, at approximately 11:00 A.M. that the laboratory failed to verify and document the minimum required twice year fungal culture interpretation accuracy for calendar years 2020, 2021, 2022, and 2023. a. Approximately 105 patient fungal culture samples were tested for the calendar years 2021, 2022 through survey date.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

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.

This STANDARD is not met as evidenced by:
Based on review of the Quality Assessment (QA) procedure; yearly QA documentation for 2020, 2021, and 2022; and interview with the office manager, the laboratory failed to follow the established QA policy. FINDINGS: 1. The laboratory failed to comply with the QA training and six-month personnel competency procedure for the six new CMAs who performed Acuderm DTM media quality control utilized in fungal culture testing. 2. The office manager confirmed on July 25, 2023, at 10:30 A.M. that the laboratory director did not perform and document the required training and six-month competency evaluations for the six new CMAs hired in the calendar year 2022. Refer to D6022.

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 the lack of Acuderm DTM media incubation storage temperature records, Acuderm DTM media manufacturer's package insert, and an interview with the office manager, the laboratory failed to monitor and document temperatures of the area where Acuderm DTM media was stored. FINDINGS: 1. The Acuderm DTM media manufacturer's package insert required 2 - 80 C and/or 15 - 300 C or 68 - 860 F storage temperatures. a. No documentation of Acuderm DTM media storage temperatures were available for review. b. Two boxes of Acuderm DTM media, lot # 185-0123, expiration date 1-26 2023, were stored in a cabinet. 2. The office manager

	<p>confirmed on July 25, 2023, at approximately 11:30 A.M. that the laboratory failed to install a thermometer and document the temperature of the area where Acuderm DTM media was stored.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Acuderm DTM media QC package insert, lack of an Individualized Quality Control Plan (IQCP) procedure, and an interview with the office manager, the laboratory failed to complete IQCP for mycology testing. FINDINGS: 1. The laboratory failed to establish a DTM media IQCP procedure including a Quality Control Procedure (QCP), Quality Assessment Procedure (IQCP), and Risk Assessment Procedure (RA) for the performance of fungal culture testing. 2. The office manager confirmed on July 25, 2023, at approximately 10:00 A.M. that the laboratory failed to establish an IQCP procedure for mycology testing.</p>
<p>D5477</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of dermatophyte media (DTM) QC records and an interview with the office manager, the laboratory failed to document the physical characteristics, perform sterility checks, and retain Acuderm DTM QC sheets for lots: 985-0113; 1257-0218; 974-1112; 1289-0818; and 975-1212 for the calendar years 2021, 2022, and 2023. FINDINGS: 1. The office manager confirmed on July 25, 2023, at approximately 10:00 A.M. that the laboratory failed to perform and document the physical characteristics, sterility checks, and retain Acuderm DTM QC sheets physical characteristics for each new batch (shipment) or lot number of DTM for the calendar years 2021, 2022, and 2023. 2. Approximately 105 patient fungal culture samples were tested for the calendar years 2021, 2022, and 2023.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the laboratory procedure manual, DTM QC records, and confirmed by interview with office manager, the laboratory director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: 1. QC and QA policy were not maintained for all phases of mycology testing. Refer to D6022. 2. Remedial action was not performed and documented when problems were identified. Refer to D6024. 3. Appropriate training was not performed and documented for the six new CMAs who performed Acuderm DTM media quality control utilized in fungal culture testing. Refer to D6029.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of QA procedures, lack of DTM QC records, and confirmed by interview with the office manager, the laboratory director failed to ensure compliance with the facility's mycology testing QA and QC procedures. Refer to D5445 and D5477.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
Based on the review of DTM media QC, temperature records, and confirmed by interview with the office manager, the laboratory director failed to ensure that remedial action was performed and documented when problems were identified. Refer to D5217, D5413, D5445, and D5477.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records, lack of training documentation, and interview with the office manager, the laboratory director failed to ensure that appropriate training was performed and documented for the six new CMAs who performed Acuderm DTM media quality control utilized in fungal culture testing. Refer to D5209.