

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2054717	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier Dermatology Associates Of Denison Pllc	Street Address, City, State 5130 Pool Road Suite 200, Denison, TX	
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
D0000	<p>Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) instructions, proficiency testing (PT) records, and confirmed in interview, the Laboratory Director and/or Testing Persons failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 Microbiology (subspecialty Mycology) events in 2021 (3rd event) and 3 of 3 Microbiology (subspecialty Mycology) events in 2022. The findings include: 1. Review of API instructions revealed: "SIGNATURES REQUIRED-For all PT results, an attestation statement must be signed by testing</p>

personnel and the laboratory director and retained for a minimum of 2 years. Either the attestation statement below or the form provided online may be used. Electronic signatures must have evidence that only the authorized person can utilize the signature." 2. Review of the Microbiology PT records from 2021 and 2022 revealed the Laboratory Director and/or Testing Person(s) failed to sign the attestation for the following events: Microbiology subspecialty Mycology 2021 - 3rd Event The laboratory director and testing person failed to sign the attestation form. Microbiology subspecialty Mycology 2022 - 1st Event The laboratory director and testing person failed to sign the attestation form. Microbiology subspecialty Mycology 2022 - 2nd Event The laboratory director and testing person failed to sign the attestation form. Microbiology subspecialty Mycology 2022 - 3rd Event The laboratory director and testing person failed to sign the attestation form. 3. During an interview on 12/06 /2022 at 11:15 a.m., Medical Assistant/Supervisor confirmed the above findings.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
 Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing (PT) for Microbiology (subspecialty Mycology) results for 2 of 3 events in 2021 (2nd and 3rd events) and 3 of 3 Microbiology (subspecialty Mycology) events in 2022. The findings include: 1. Review of API instructions revealed: "PERFORMANCE REVIEW AND CORRECTIVE ACTION After reviewing the evaluations reports, complete the information below and retain this form along with the enclosed reports for your records." 2. Review of API PT records for 2021 and 2022 revealed the laboratory did not ensure the laboratory director or designee reviewed and documented their evaluation of Microbiology (subspecialty Mycology) PT results as follows: Microbiology subspecialty Mycology 2021 - 2nd Event The Laboratory Director or designee failed to sign the performance evaluation. Microbiology subspecialty Mycology 2021 - 3rd Event The Laboratory Director or designee failed to sign the performance evaluation. Microbiology subspecialty Mycology 2022 - 1st, 2nd, and 3rd Events There were no performance evaluation sheets attached to the PT records for the Microbiology events for 2022. The surveyor asked for documentation of the laboratory's performance review for the 2022 events. None was provided. The Laboratory failed to review and evaluate the results obtained on proficiency testing. 3. During an interview on 12/06/2022 at 11:15 a.m., Medical Assistant/Supervisor confirmed the above findings.

D5411

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, quality control (QC) records, and confirmed in interview, the laboratory failed to perform ACU-DTM media QC according to the manufacturer's instructions in 2021 and 2022. The findings include:

1. Review of the ACU-DTM QC Kit instructions for use revealed: "Expected Results Organism- Trichophyton mentagrophyte Incubation Period- 7 days Growth- Yes Media Color change- Yes Read on Days- 5-7 Description of Growth- Surface white and downy. Change media to red. Organism- E. coli Incubation Period- 7 days Growth- No Media Color change- No Read on Days- 5-7 Description of Growth- No growth Organism- Aspergillus niger Incubation Period- 7 days Growth- Yes Media Color change- No Read on Days- 5-7 Description of Growth- Surface at first white, then shade of black. Organism- Candida albicans Incubation Period- 48 hrs Growth- Yes Media Color change- No Read on Days- 1-2 Description of Growth- Cream color, pasty smooth. May turn the media red after 48 hrs." 2. Review of the laboratory QC logs titled "Results Log-Qualitative Test" from 2021 and 2022 revealed the following:
2021 A. "E. coli" Date of Inoculation: 06/09/2021 Date of Reading: BLANK Quality Control ID: BLANK Test Batch Lot Number: 59301741 Growth: No Media Color Change: No "Aspergillus" Date of Inoculation: 06/09/2021 Date of Reading: BLANK Quality Control ID: BLANK Test Batch Lot Number: 63359091 Growth: Yes Media Color Change: No "Trichophyton" Date of Inoculation: 06/09/2021 Date of Reading: BLANK Quality Control ID: BLANK Test Batch Lot Number: 3318554 Growth: Yes Media Color Change: Yes "Candida" Date of Inoculation: 06/09/2021 Date of Reading: BLANK Quality Control ID: D-1412-0321 Test Batch Lot Number: 58642667 Growth: Yes Media Color Change: No B. "E. coli" Date of Inoculation: 07/01/2021 Date of Reading: 07/14/2021 (13 days after inoculation) Quality Control ID: D-1414-0421 Test Batch Lot Number: "E coli" Growth: No Media Color Change: No "Aspergillus" Date of Inoculation: 07/01/2021 Date of Reading: 07/14/2021 (13 days after inoculation) Quality Control ID: D-1414-0421 Test Batch Lot Number: "Aspergillus" Growth: Yes Media Color Change: No "Trichophyton" Date of Inoculation: 07/01/2021 Date of Reading: 07/14/2021 (13 days after inoculation) Quality Control ID: D-1414-0421 Test Batch Lot Number: "Trichophyton" Growth: Yes Media Color Change: Yes "Candida" Date of Inoculation: 07/01/2021 Date of Reading: 07/14/2021 (13 days after inoculation) Quality Control ID: D-1414-0421 Test Batch Lot Number: "Candida" Growth: Yes Media Color Change: No 2022 "E. coli" Date of Inoculation: 05/04/2022 Date of Reading: 05/18/2022 (14 days after inoculation) Quality Control ID: D-1414-0521 Test Batch Lot Number: 68201421 Growth: Yes Media Color Change: Yes Note: Based on the manufacturer's expected results for the above organism, QC failed. "Aspergillus" Date of Inoculation: 05/04/2022 Date of Reading: 05/18/2022 (14 days after inoculation) Quality Control ID: D-1414-0521 Test Batch Lot Number: 42279090 Growth: No Media Color Change: No Note: Based on the manufacturer's expected results for the above organism, QC failed. "Trichophyton" Date of Inoculation: 05/04/2022 Date of Reading: 05/18/2022 (14 days after inoculation) Quality Control ID: D-1414-0521 Test Batch Lot Number: 71942701 Growth: No Media Color Change: No Note: Based on the manufacturer's expected results for the above organism, QC failed. "Candida" Date of Inoculation: 05/04/2022 Date of Reading: 05/18/2022 (14 days after inoculation) Quality Control ID: D-1414-0521 Test Batch Lot Number: 50462711 Growth: Yes Media Color Change: Yes Note: Based on the manufacturer's expected results for the above organism, QC failed. The laboratory failed to document and read ACU-DTM media QC at the timeframes specified by the manufacturer. The laboratory failed to perform ACU-DTM media QC according to the manufacturer's instructions. 3. During an interview on 12/06/2022 at 11:46 a.m., the Medical Assistant/Supervisor confirmed the above findings.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation and confirmed in interview, the laboratory failed to ensure tissue marking dyes stored in secondary containers were labeled with proper identification and poured/expiration dates for 4 of 4 dyes. The findings include: 1. During a tour of the laboratory on 12/06/2022 at 12:37 p.m., the surveyor observed 5 unlabeled plastic jars in a drawer as follows: 1 jar containing red dye 1 jar containing green dye 1 jar containing blue dye 1 jar containing black dye 1 jar containing clear liquid During an interview on 12/06/2022 at 12:37 p.m., the surveyor asked the Medical Assistant/Supervisor what the clear liquid was, and she stated that it was water. The laboratory failed to label the secondary containers with the name of the material, lot numbers, and poured/expiration dates, as applicable. Without proper labeling, the tissue marking dyes could not be linked to their original containers. 2. During an interview on 12/06/2022 at 12:42 p.m., the Medical Assistant/Supervisor confirmed the above findings.