

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0501845	(X3) Date Survey Completed 11/08/2021
Name of Provider or Supplier Gregory W Thompson Md Pa	Street Address, City, State 14615 San Pedro Ave #200, San Antonio, 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>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 Dallas Regional Office (RO) for referral to the Office of 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>
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 surveyor's observations, review of the laboratory's CMS form 116, review of the laboratory's twice annual accuracy verification records for 2020 and 2021 and staff interview it was determined the laboratory failed to document performance of twice annually verifying mycology cultures' accuracy for recovery of dermatophyte fungi. Findings included: 1. Surveyor's observations on 11/08/2021 at 13:30 hours in the laboratory revealed a vial of Dermatophyte Testing Medium used for fungal cultures of dermatophytes, labeled with patient information and date of collection. Further investigation revealed the sample was to be incubated at room temperature for a total of 14 days. The sample was collected on 11/01/2021 and was on its 7th day of incubation at the time of the survey. 2. Review of the laboratory's CMS form 116</p>

submitted at the time of the survey (signed by the laboratory director on 11/05/2021) revealed the laboratory performed approximately 24 mycology tests/cultures annually. 3. Review of the laboratory's twice annual accuracy verification records for 2020 and 2021 revealed no documentation of verifying twice annually the accuracy of the fungal cultures' ability to recover dermatophytes. 4. In an interview on 11/08/2021 at 1400 hours in the laboratory the Medical Assistant (as described on the Survey Entrance Conference Document) stated that the laboratory did not perform twice annual accuracy verification for fungal/dermatophyte cultures. This confirmed the findings.

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:
A. Based on review of the laboratory's Acuderm Inc. ACU-DTM Dermatophyte Test Medium package insert (IFU-001) review of the laboratory's temperature logs for 2021, review of the CMS form 116 and staff interview it was determined the laboratory failed to establish and monitor mycology/fungal culture incubation temperature. Findings included: 1. Review of the Acuderm Inc. ACU-DTM Dermatophyte Test Medium package insert revealed: "INCUBATION Incubation at room temperature, 20-30C (68F-86F) is satisfactory for growth of most dermatophytes. Lower temperatures may result in slower growth. Optimal growth occurs at 29C (84F)." 2. Review of the laboratory's temperature logs revealed no definition or documentation of temperature range acceptability for mycology/fungal culture incubation. 3. Review of the laboratory's CMS form 116 (submitted at the time of the survey) revealed the laboratory performed approximately 24 mycology/fungal cultures a year. 4. In an interview on 11/08/2021 at 1400 hours in the laboratory the Medical Assistant confirmed that the laboratory did not establish acceptable temperature range and did not monitor temperatures for mycology/fungal cultures. Legend: C = Celsius F = Fahrenheit

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Acuderm Inc. ACU-DTM Dermatophyte Test Medium package insert (IFU-001), review of the laboratory's quality control (QC) records for 2021 and staff interview it was determined the laboratory failed to document quality control for the ACU-DTM media's ability to support/select for growth of dermatophyte fungi. Note: The laboratory did not establish Individualized Quality Control Plan (IQCP) for media, therefore each batch/lot of media must have documentation of quality control for its ability to support growth or selectivity for specific organisms. Findings included: 1. Review of the ACU-DTM Dermatophyte Test Medium package insert revealed: a. "QUALITY CONTROL CLIA requires the end user to perform a minimum of positive and negative control on each new lot or batch purchased." b. QC requirements included culturing specific organisms with the following expected results: Trichophyton mentagrophyte - positive control (dermatophyte) - Media color change: Turns Red E. coli - negative control (bacteria) - Media color change: No 2. Review of the laboratory's QC records for 2021 revealed no documentation of QC being performed for the ACU-DTM media. 3. In an interview on 11/08/2021 at 1400 hours in the laboratory the Medical Assistant stated that she was not aware of the media's QC requirements. This confirmed the findings.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on surveyor's observations, review of the Acuderm Inc. ACU-DTM Dermatophyte Test Media packaging, review of the laboratory's temperature charts for August through October of 2021 and staff interview it was determined the laboratory failed to document corrective actions for Dermatophyte Test Media storage outside of manufacturer required temperature range for 20 of 91 days reviewed. Findings included: 1. Surveyor's observations on 11/08/2021 at 1330 hours in the laboratory revealed a box of ACU-DTM Dermatophyte Test Media (Lot# D-1409-0321, expiration 2023-03-08) stored in the refrigerator. 2. Review of the of ACU-DTM Dermatophyte Test Media packaging revealed storage temperature requirement to be: "REFRIGERATE: Store at 2-8C (35-46F). DO NOT FREEZE." 3. Review of the laboratory's temperature charts for August through October of 2021 revealed: a. The temperature logs did not have a definition for acceptable temperature range for the refrigerator. b. Refrigerator temperature was out of the required 2-8C range for ACU-DTM media on the following days: 08/02/2021 temperature was 1C 08/11/2021 temperature was 1C 08/16/2021 temperature was 1C 08/18/2021 temperature was 1C 08/20/2021 temperature was 1C 08/23/2021 temperature was 1C 09/01/2021 temperature was 1C 09/03/2021 temperature was 1C 09/06/2021 temperature was 1C 09/13/2021 temperature was 1C 09/15/2021 temperature was 1C 09/22/2021 temperature was 1C 09/29/2021 temperature was 1C 10/06/2021 temperature was 1C 10/08/2021 temperature was 1C 10/11/2021 temperature was 1C 10/15/2021 temperature was 1C 10/25/2021 temperature was 1C 10/27/2021 temperature was 1C 10/29/2021 temperature was 1C c. Laboratory's temperature records revealed no documentation of corrective action for the days the temperature was out of manufacturer's required range. 4. In an interview on 11/08/2021 at 1400 hours in the

laboratory the Medical Assistant stated that she was unaware of the media's temperature requirements, and after reviewing the temperature logs, confirmed the findings. Legend: C = Celsius F = Fahrenheit

D6020

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 program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records, review of the manufacturer's package inserts for the Acuderm Inc. ACU-DTM Dermatophyte Test Medium and staff interview it was determined the laboratory director failed to ensure QC was established and maintained for the ACU-DTM media. Refer to D5477.