Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2057348	06/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cockerell Dermatopathology, Pa	2110 Research Row, Dallas, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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 to be 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 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory proficiency testing records (2019-2020) and confirmed in staff interview, the laboratory failed to verify the accuracy of non-regulated KOH (potassium hydroxide) at least twice annually for 2019 and 2020. Findings Included: 1. Review of the laboratory policy, "KOH Touch Prep/ Smear Slides for Scabies" (Approved by the laboratory director on 07/01/13), revealed the laboratory possessed no procedure for twice annual accuracy assessment of the non-regulated analyte. 2. Review of laboratory proficiency testing records for 2019-2020, revealed the laboratory failed to perform twice annual accuracy assessment for KOH

	in 2019 and 2020. 3. In an interview with the general supervisor at 11:51 A.M on 6/3 /2021, in the conference room, the laboratory manager was asked to provide documentation of twice annual accuracy assessment for KOH. The laboratory manager stated the laboratory did not perform twice annual accuracy assessment of KOH. The supervisor stated the facility rarely obtained specimens for KOH and the sample sizes received were typically inadequate for repeat testing. This confirmed the above 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: Based on direct observation, review of the operator's manual for: Tissue-Tek AutoTEC, Tissue-Tek Xpress x120, and Tissue-Tek VIP 5, review of laboratory environmental records (1/2021-5/2021) and confirmed in staff interview, the laboratory failed to ensure room temperature and humidity ranges were within manufacturer's specifications for operating conditions for 5 of 5 months. Findings Included: 1. During a tour of the laboratory, the inspector observed the following instruments in use: a. Tissue-Tek AutoTEC #1 Serial Number: 70900073-0216 b. Tissue-Tek AutoTEC #2 Serial Number: 70900076-0316 c. Tissue-Tek AutoTEC #3 Serial Number: 70900077-0316 d. Tissue-Tek Xpress x120 #1 Serial Number: 77200064 e. Tissue-Tek Xpress x120 #2 Serial Number: 77200065 f. Tissue-Tek VIP 5 #1 Serial Number: 52151496-0108 g. Tissue-Tek VIP 5 #2 Serial Number: 52151493-0108 2. Review of the Tissue-Tek AutoTEC operator's manual (Revised 04 /1/2011), stated the following operating temperature and humidity ranges: Operating Temperature: 15 to 35C Operating Humidity: 20 to 85% 3. Review of the Tissue-Tek Xpress x120 operator's manual (Revised 04/10/2012), stated the following operating temperature and humidity ranges: Operating Temperature: 15 to 35 C Operating Humidity: 30 to 85% 4. Review of the Tissue-Tek VIP 5 operator's manual (revised 05 /16/2001), stated the following operating humidity range: Operating Humidity: 30 to 85% 5. Review of the laboratory's environmental records (1/2021-5/2021) revealed the laboratory defined their acceptable temperature range as 50-86F (10-30C) and acceptable humidity range as 5-90%. The laboratory failed to ensure the room temperature and humidity ranges were within manufacturer's specifications for all instrumentation utilized in the laboratory. 6. In the exit conference with the laboratory representatives at 1:15 P.M on 6/3/2021, in the conference room, the laboratory representatives were presented with the above findings. The general supervisor acknowledged the laboratory failed to ensure room temperature and humidity ranges were within Tissue-Tek AutoTEC, Tissue-Tek Xpress x120, and Tissue-Tek VIP 5 manufacturer's specifications for 5 of 5 months. This confirmed the above findings.
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 manufacturer's instructions, laboratory policy, laboratory records (08/03/2019-10/16/2020) and confirmed in staff interview, it was revealed that the laboratory failed to check each new lot/ new shipment of testing media for its ability to produce a biochemical response for 7 of 7 lots of Dermatophyte Test Medium. Findings included: 1. The manufacturer's instructions for BBL Dermatophyte Test Medium (8814091, Rev.03, April 2015) stated the following: "I. Introduction: Dermatophyte Test Medium (DTM, modified with chloramphenicol is a selective and differential medium used for the detection and presumptive identification of dermatophytes from clinical and veterinary specimens. II. Performance Test Procedure: 1. Inoculate representative samples with the cultures listed below .... Apsergillus brasiliensis; ATCC 16404; Recovery-Inhibition (partial to complete); Medium Coloration-N/A Escherichia coli; ATCC 25922; Recovery-Inhibition (partial to complete); Medium Coloration-N/A Microsporum audouinii; ATCC 9079; Recovery-Moderate to heavy growth; Medium Coloration-pink to red Pseudomonas aeruginosa; ATCC 10145; Recovery-Inhibition (partial to complete); Medium Coloration-N/A Trichophyton mentagrophytes; ATCC 9533; Recovery-Moderate to heavy growth; Medium Coloration-pink to red ..." 2. The laboratory policy titled, "Mycology Quality Control" (Signed by the laboratory director 08/03/2020), stated, "V. Quality Control: Each lot of commercially prepared media is inspected upon receipt. Each new lot number of culture tubes is tested to ensure sterility and supported growth of the dermatophytes ..." This policy failed to ensure quality control was performed for each new lot/new shipment of testing media to ensure its ability to produce a biochemical response. 3. Review of the laboratory record titled, "Attachment A Mycology Sterility Log", revealed the following: a. Date: 08/23/2019 Lot Number: 9169847 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS19-82655 b. Date: 11/14/2019 Lot Number: 9260531 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS19-119000 c. Date: 01/29/2020 Lot Number: 93337779 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS19-153499 d. Date: 04/22/2020 Lot Number: 0009453 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS20-32858 e. Date: 07/22/2020 Lot Number: 0100064 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS20-54495 f. Date: 09/10/2020 Lot Number: 0218665 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS20-76671 g. Date: 10/16/2020 Lot Number: 0245064 Negative Growth (-) Positive Growth (+) Positive Culture Used for Control: CS20-91285 The laboratory failed to ensure quality control was performed for each new lot/new shipment of testing media to ensure its ability to produce a biochemical response. 4. In an interview on 06/03/2021 at 11:28am in the conference room, the Laboratory Manager was asked to provide documentation of quality control for each new lot/new shipment of DTM to produce a biochemical response. No documentation was provided. She stated that the laboratory only performed quality control to ensure growth or no growth. This confirmed the above findings. WORD KEY: ATCC=American Type Culture Collection N/A=not applicable