# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2057348	**(X3) Date Survey Completed** 01/13/2023
Name of Provider or Supplier Cockerell Dermatopathology, Pa	**Street Address, City, State** 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	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.
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 the Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory proficiency testing (PT) records, and confirmed in interview, the laboratory failed to verify the accuracy of KOH preparations at least twice annually in 2022. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed KOH preparations. 2. Review of the laboratory's PT records from 2022 revealed the following unsatisfactory scores: WSLH PT 2022-MicroQA1 Module: 6230, KOH Slides Analyte score: 66% WSLH PT 2022- MicroQA2 Module: 6230, KOH Slides Analyte score: 66% 3. Further review of the laboratory's PT records from 2022

	revealed no documentation of remedial action for the above failures. The surveyor requested documentation of remedial action. None was provided. 4. During an interview on 01/13/2023 at 10:39 a.m., the Laboratory Manager confirmed the above findings. Key: KOH- Potassium hydroxide WSLH- Wisconsin State Laboratory of Hygiene
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: I. Based on review of laboratory policy, manufacturer's instructions, quality control (QC) records, and confirmed in interview, the laboratory failed to perform Dermatophyte Test Medium (DTM) QC according to the manufacturer's instructions for 7 of 7 DTM lot numbers in 2022. The findings include: 1. Review of the laboratory policy titled "Mycology Quality Control" revealed: "V. QUALITY CONTROL: Each new lot number and shipment of commercially prepared media is inspected upon receipt and tested with known positive and negative organisms to ensure quality, sterility and supported growth of dermatophytes. VI. PROCEDURE: A. Each new lot and shipment of commercially prepared media is inspected upon receipt for the following deficiencies: cracked tubes, unequal filling of tubes, cracked medium in tubes, excessive bubbling or pitting of media, and contamination. B. Each new lot and shipment of culture tubes is tested to ensure supported growth of dermatophytes. 1. Two tubes from each different lot number and shipment is inoculated. 2. One tube is inoculated with a known positive organism, Trichophyton mentagrophytes and the second tube is inoculated with a known negative organism, Escherichia coli. 3. Both tubes are dated fifteen working days from inoculation date and incubated at 22C-25C with lids of the tubes kept slightly loose to maintain aerobic conditions ..." 2. Review of the Hardy Diagnostics DTM instructions for use revealed: "QUALITY CONTROL ... Test Organism- "Trichophyton mentagrophytes ATCC 9533" Time- "4-7 days" Temperature- "15-30C" Results- "Growth; white colonies and a red color change develops in the medium surrounding the colonies" Test Organism- "Escherichia coli ATCC 25922" Time- "24 hr" Temperature- "15-30C" Results- "Inhibited" 3. Review of the laboratory QC log titled "Mycology Quality Control Log" from 2022/2023 revealed the following: Date DTM Tubes Received: 01/13/2022 DTM Tubes Lot Number: 493420 KWIK-STIK Lot Number Trichophyton mentagrophyte (+): 442-86-4 KWIK-STIK Lot Number Escherichia coli (--): 204-34-3 3 week check date: 02/14/2022 Negative Growth (--): - Positive Growth (+): + No Color Change (--): - Color Change (+): + Date DTM Tubes Received: 02/16/2022 DTM Tubes Lot Number: 1356881 KWIK-STIK Lot Number Trichophyton mentagrophyte (+): 442-86-4 KWIK-STIK Lot Number Escherichia coli (--): 204-34-3 3 week check date: 03/09/2022 Negative Growth (--): - Positive Growth (+): + No Color Change (--): - Color Change (+): + Date DTM Tubes Received: 05/13/2022 DTM Tubes Lot Number: 496475 KWIK-STIK Lot Number Trichophyton mentagrophyte (+): 442-88-3 KWIK-STIK Lot Number Escherichia coli (--): 204-34-7 3 week check date: 06/03/2022 Negative Growth (--): - Positive Growth (+): + No Color Change (--): - Color Change (+): + Date DTM Tubes Received: 08/03/2022 DTM Tubes Lot Number: 505533 KWIK-STIK Lot Number

	Trichophyton mentagrophyte (+): 442-88-3 KWIK-STIK Lot Number Escherichia coli (--): 204-34-7 3 week check date: 08/24/2022 Negative Growth (--): - Positive Growth (+): + No Color Change (--): - Color Change (+): + Date DTM Tubes Received: 09/29/2022 DTM Tubes Lot Number: 507338 KWIK-STIK Lot Number Trichophyton mentagrophyte (+): 442-89-3 KWIK-STIK Lot Number Escherichia coli (--): 204-35-5 3 week check date: 10/24/2022 Negative Growth (--): - Positive Growth (+): + No Color Change (--): - Color Change (+): + Date DTM Tubes Received: 11/01/2022 DTM Tubes Lot Number: 510152 KWIK-STIK Lot Number Trichophyton mentagrophyte (+): 442-89-3 KWIK-STIK Lot Number Escherichia coli (--): 204-35-5 3 week check date: 11/23/2022 Negative Growth (--): - Positive Growth (+): + No Color Change (--): - Color Change (+): + Date DTM Tubes Received: 12/22/2022 DTM Tubes Lot Number: 513921 KWIK-STIK Lot Number Trichophyton mentagrophyte (+): 442-89-5 KWIK-STIK Lot Number Escherichia coli (--): 204-35-5 3 week check date: 01/24/2023 Negative Growth (--): BLANK Positive Growth (+): BLANK No Color Change (--): BLANK Color Change (+): BLANK The laboratory failed to read DTM QC at the timeframes specified by the manufacturer. The laboratory failed to perform DTM media QC according to the manufacturer's instructions. 4. During an interview on 01/13/2022 at 12:32 p.m., the Laboratory Manager confirmed the above findings. Key: -/(--): Negative +/(+): Positive II. Based on review of the manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to interpret Dermatophyte Test Medium (DTM) results according to the manufacturer's instructions for 5 of 5 patients (random sampling) in 2022 and 2023. The findings include: 1. Review of the Hardy Diagnostics DTM instructions for use revealed: "PROCEDURE ... Incubate the media at room temperature (15-30C.), aerobically, for up to fourteen days ... INTERPRETATION OF RESULTS Media should be examined daily for up to fourteen days ... LIMITATIONS ... False-positive reactions may result, if interpretations are made beyond 14 days of incubation. An alkaline reaction will eventually be produced by most non-dermatophytic fungi that are capable of growing on this medium ..." 2. Review of patient test records from 2022 revealed the following 5 patients (random sampling) whose DTM cultures were reported when the manufacturer's interpretation timeframe of 14 days was not followed: Case Number: CS22-151689 Date Received: 12/09/2022 "3 Week Check": 12/30/2022 (specimen read 21 days after inoculation) Date Reported: 01/03/2023 Case Number: CS22-151690 Date Received: 12/09/2022 "3 Week Check": 12/30/2022 (specimen read 21 days after inoculation) Date Reported: 01/03/2023 Case Number: CS22-151691 Date Received: 12/09/2022 "3 Week Check": 12/30/2022 (specimen read 21 days after inoculation) Date Reported: 01/03/2023 Case Number: CS22-151692 Date Received: 12/09/2022 "3 Week Check": 12/30/2022 (specimen read 21 days after inoculation) Date Reported: 01/10/2023 Case Number: CS22-152066 Date Received: 12/12/2022 "3 Week Check": 01/02/2023 (specimen read 21 days after inoculation) Date Reported: 01/10/2023 3. During an interview on 01/13/2022 at 12:32 p.m., the Laboratory Manager confirmed the above findings. Key: ATCC-American Type Culture Collection