Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1053408	05/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rodgers Dermatology	3880 Parkwood Blvd,Suite 102, Frisco, 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.
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 temperature logs, laboratory records, and staff interview, the laboratory failed to ensure the proper storage conditions were maintained for potassium hydroxide (KOH) reagents for 38 of 43 days in 2021

	(random review September-October), and 38 of 46 days in 2022 (random review March-May). Findings: 1. During a tour of the second laboratory area (nursing station) on 05/05/2022 at 9:50 am, the following was observed stored on the counter next to the microscope: 1 bottle of Chlorazol Black E, Lot# 1120, expiration date 04 /30/2023, store at room temperature 2. Review of the laboratory's temperature logs revealed a room temperature requirement for the nursing station of 68-77F. Further review of the temperature log revealed the following dates in 2021 and 2022 (random review) the laboratory failed to document the room temperature in the nursing station: 2021 September: 1, 2, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 20, 21, 22, 23, 27, 28, 29, 30 October: 1, 4, 5, 6, 7, 8, 11, 12, 14, 15, 18, 19, 21, 22, 25, 26, 28, 29 2022 March: 1, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 24, 25, 28, 29, 31 April: 1, 4, 5, 7, 8, 11, 12, 14, 15, 18, 19, 21, 22, 25, 26, 28, 29 May: 2, 3 4. Review of the laboratory's annual test volume revealed the laboratory performed 100 KOH tests. 5. During an interview on 05/05/2022 at 9:55 am, the Histotechnician confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, potassium hydroxide (KOH) patient logs, patient charts and in interview with staff, the laboratory failed to ensure 2 of 10 patients KOH results were transcribed accurately to the final test report (03/2022-04 /2022). Findings: 1. Review of the laboratory's policy "KOH Prep" stated: "KOH tests will be documented in the patient's chart as well as a running log, kept in the nurse's station." 2. A random review of "KOH Patient Log" from 03/2022 through 04/2022 revealed the following patient KOH results documented: Patient #1 "Date: 04/08 /2022; Patient Name: [XX]; KOH (+/-): +" (positive) Patient #2 "Date: 04/21/2022; Patient Name: [XX]; KOH (+/-): - " (negative) The laboratory's practice was documenting the patient's result in the log and then transcribing it manually or by dictation in the patient's chart ("Visit Note"). The laboratory was asked to provide the above-mentioned patients charts to review the KOH results for those dates. The charts were provided, and KOH results were transcribed in the patients charts as follows: Patient #1: MRN (medical record number): MM0000004243; Visit Note date: 04/08 /2022 "Plan: KOH Prep. A KOH prep was ordered and evaluated from the left rib cage. A 15-blade scalpel was used to scrape the skin. The skin scrapings were placed on a glass slide, covered with a coverslip and a KOH solution was applied. Examination of the slide showed: branching hyphae." Patient #2: MRN: MM0000013000; Visit Note date: 04/21/2022 "Plan: KOH Prep. A KOH prep was ordered and evaluated from the left distal pretibial region. A 15-blade scalpel was used to scrape the skin. The skin scrapings were placed on a glass slide, covered with a coverslip and a KOH solution was applied. Examination of the slide showed: +/- results." The final report test results did not reflect results in the patient log. The

	laboratory failed to ensure test results were transcribed accurately when entered into the patient chart. 3. During an interview on 05/05/2022 at 10:05 am, the Histotechnician reviewed and confirmed the above findings.