Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2098645	09/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology, Pa	4100 Hwy 377, Brownwood, 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 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 the CMS (Center for Medicaid & Medicare Services) 116 form, laboratory policy, proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated scabies procedures at least twice annually for 1 of 2 testing events in 2020 and 1 of 2 testing events in 2021. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed scabies procedures. 2. Review of the laboratory policy titled "KOH/Scabies" revealed the following: "PROCEDURE: Performing the KOH/Chlorazol Black E Preparation, Charting KOH/Chlorazol Black E reports, CLIA

	compliance Physicians and mid-level providers ... CLIA required paperwork: CLIA requires evaluations of all providers performing medium level complexity tests biannually. To fulfill this requirement each provider will receive an email from the Epiphany Dermatology Compliance Manager biannually containing 10 sets of images along with 4 associated questions following each image. The quiz is to be completed within the time range set by the Compliance Manager. All results will be maintained in an electronic file and available upon request. In some practices a second provider may be available for peer review of the slide at the time of diagnosis. If available, the name of the second provider as well as whether or not they concur with the diagnosis will be recorded. This record review may be used as a competency assessment in lieu of the electronic quiz. All results will be maintained and available upon request. Training sessions will be provided for all employees found to be non-competent." 3. Review of the laboratory's proficiency testing records revealed the laboratory performed proficiency testing events for scabies and KOH procedures for two-time periods January through June (event 1) and July through December (event 2). Review of event 2 in 2020 and event 1 in 2021 revealed there was no documented proficiency testing for scabies procedures. The laboratory failed to verify the accuracy of scabies procedures at least twice annually in 2020 and 2021. 4. During an interview on 09/28 /2021 at 12:25 pm, the Office Manager 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 review of laboratory policy, laboratory logs, and confirmed in interview, the laboratory failed to document and monitor the room temperature, humidity and cryostat temperature for 1 of 4 days in 2021 (September). Findings: 1. Review of laboratory policy titled "Mohs Procedure" revealed: "Cryostat Use Protocol Temperature is recorded daily on the Quality control log. Temperature range is -15 to -30C for cryostat." 2. Review of the laboratory logs titled "Quality Control Log" stated the following: "Must be recorded/performed each day of Moh's Surgery (a check indicates that the action has been performed) ... Lab Temperature- Normal values: 68-77 degrees Fahrenheit * All values on this row are in Fahrenheit Lab Humidity- Normal values: not to exceed 60 percent (non-condensing) * All values on this row are percentages Cryostat Temperature- Normal values: -15 to -30 degrees Celsius * All values on this row are in Celsius" Further review of the "Quality Control Log" revealed there was no documented evidence for room temperature, humidity or cryostat temperature on 09/17/2021. The laboratory failed to monitor and document the room temperature, humidity, cryostat temperature each day MOHs surgery was performed. 3. During an interview on 09/28/2021 at 11:45 am, the Office Manager confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policy, Quality Control Log, patient test reports and confirmed in interview, the laboratory failed to test and document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for 1 of 4 days in 2021 (September). Findings: 1. Review of the laboratory's policy "Mohs Procedure" revealed: "2. Manual and automatic H and E Staining ... Expected results Crisp nuclear detail (Hematoxylin) purple in color with a high contrast counterstain (Eosin) pink in color Quality Control Each day of Mohs surgery, the Mohs technician will fill out the QC log per the Mohs surgeon regarding the acceptability of the control slide/staining acceptability" 2. Review of the laboratory's "Quality Control Log" did not include for each day of use, documentation of the intended reactivity for the H&E stain on the following days patients were tested and reported in 2021 (September): 09/17/2021 Patient IDs: BW21-324, BW21-325, BW21-326, BW21-327, BW21-328, BW21-329, BW21-330, BW21-331 3. During an interview on 09/28/2021 at 11:45 am, the Office Manager confirmed the above findings.