Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2091398	07/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology Pa	211 N Industrial Drive, Waco, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, observation, requisition slips, presurvey paperwork, and interview, the laboratory failed to verify at accessioning that the name on the requisition slip matched the name on the vials for two of two cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled "Accessioning Protocol," revised 08/15/2023, Procedure stated, "1. Specimens received from outside clinics are delivered to the laboratory... In the laboratory Specimen container labels are compared to the accompanying requisition to ensure accuracy." B. During a tour of the laboratory on July 24, 2024 at 0955 hours KM was observed removing two of two requisition slips and vials from biohazard bags and laying the requisition slips out on the counter with the vials from the bags, and ER was putting labels on the requisition slips and vials. No one was ensuring the vials matched the slips, as listed by date of service and order number: Date of Service Order Number 1. 07/22/2024 523618 2. 07/22/2024 524036 C. Review of the presurvey paperwork of the test count worksheet showed an estimated annual test volume of 247,118 H&E blocks. D. Interview with the Accessioning Supervisor on

	July 24, 2024 at 1000 hours in the laboratory acknowledged it was KM's responsibility to verify the slips matched the vials. Interview with the Compliance Specialist on July 24, 2024 at 1005 confirmed the 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 the manufacturer's instructions, quality control (QC) records, presurvey paperwork, and interview, the laboratory failed to document the reactivity of the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for their quality control used in diagnostic interpretations in dermatopathology for 23 out of 23 months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled "Laboratory Quality Assurance," revised 08/15/2023, under Procedure stated, "Daily slide Quality Control: Hematoxylin and Eosin: Epiphany Dermatology uses a QC log filled out by a dermatopathologist or dermatologist on each day of microscopic examination is performed. Overall slide quality will be assessed. Some Lab Directors may opt to include columns specific to nuclear detail and cytoplasmic staining. Each patient case will act as an H & E control. Nuclei should stain blue. Cytoplasmic components should stain pink to light red..." B. Review of the Epiphany Dermatology Daily Processing/ Staining Quality Control log from 08/01/2022 to 06/30/2024 showed Acceptable or Unacceptable for the stain, but did not define what was considered acceptable. C. Review of the presurvey paperwork of the test count worksheet showed an estimated annual test volume of 247,118 H&E blocks. D. Interview with the Compliance Specialist on July 23, 2024 at 1405 hours in the conference room confirmed what is considered acceptable is not on the form.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, test reports, quality control (QC) records, pre-survey paperwork, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Special stains for the diagnostic interpretation of dermatopathology specimens for three out of 20 reports reviewed. Finding follow. A. Review of the laboratory's policy and procedure titled "Laboratory Quality Assurance," revised 08/15/2023, under

	Procedure stated, "Special Stains: The Dermatopathologist and/or Lab Director reviews the special stains daily and verifies acceptable performance with documentation on the special stain log.... Immunohistochemistry: The Dermatopathologist and/or Laboratory Director reviews the special stains daily and verifies acceptable performance with documentation on the immunohistochemistry (IHC) log." B. Random review of test reports from 07/25/2022 - 06/27/2024 with Immunohistochemical (IHC)/Special stains against the Dermatologist QC Log revealed three out of 20 reports did not include QC for the intended reactivity to ensure predictable staining characteristics for the following IHC/Special stains, as listed by date reported, accession number, and IHC/special stain: Date Reported Accession number IHC/Special Stain 1. 04/25/2023 SUR23-39143 Alcian Blue 2. 01 /10/2024 SUR24-835 Factor XIIIa, SMA 3. 06/05/2024 SUR24-62885 CD3 C. Review of the presurvey paperwork of the test count worksheet showed an estimated annual test volume of 321 for Alcian Blue, 199 for Factor XIIIa, 233 for SMA, and 380 for CD3. D. Interview with the Compliance Specialist on July 24, 2024 at 1125 hours in the conference room confirmed the findings. KEY: SMA = Smooth Muscle Actin