Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2123056	(X3) Date Survey Completed 03/05/2019
Name of Provider or Supplier Epiphany Dermatology Of New Mexico, Llc	**Street Address, City, State** 5600 Eubank Bld Ne, # 110, Albuquerque, NM	

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 following deficiencies were cited as the result of a complaint survey on 03/04/19 for 42 CFR part 493 Laboratory Requirements. Intake NM00035515 was substantiated.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the review of patient medical records, laboratory policies, and interviews with laboratory staff and Patient #1's (P1) wife, the laboratory failed to ensure all staff followed written policies ensuring positive specimen identification throughout the collection and reporting process for 1 (P1) of 9 (P1-P9) patient records reviewed. This failed practice resulted in the reference laboratory reporting results for a misidentified biopsy site. Findings are: A. Review of medical records revealed discrepancies related to the biopsy site identification in the visit notes and in the laboratory reports for 1 (P1) of 9 (P1-P9) patients. 1. The visit note (patient medical record) for P1 dated 01/31 /19 indicated the following: a. "Neoplasm of Uncertain Behavior located on the right ear." "Plan: Biopsy by Shave Method. Location (A) right ear." b. Actinic Keratoses "distributed on the left ear, right lip and left zygoma(cheekbone)" c. The scribe (person responsible for recording the office visit) was identified as MA1 (Medical Assistant 1) and the provider was identified as PA1 (Physician Assistant 1). No other staff were present. 2. The visit note diagrams for P1 indicated a biopsy was taken from behind the patient's right ear. 3. The 2 photographs taken by clinic staff on 01/31 /19 at 11:22 am were the rear view of the patient's left ear, not the right ear. 4. The original reference laboratory pathology report dated 02/04/19 indicated the biopsy site

	as the right ear. A corrected report was issued on 02/28/19 indicating the biopsy site was the left ear. The diagnosis was a malignancy, a Squamous Cell Carcinoma. B. Review of a letter dated 02/13/19 sent to P1 from PA1 indicated the following; "I am writing to you in regards to your biopsy results from your right hip & right forearm. The results came back as Squamous Cell Carcinoma. We need to set up an appointments(sic) to treat this skin cancer." C. During interview on 02/26/19 at 8:37 am, P1's wife stated that she received the 02/13/19 letter and noted the biopsy site discrepancies. She stated she called the office on 02/21/19 and on 02/22/19 and left messages for a return call. When she did get a return call, the medical assistant (MA2) indicated that the biopsy source was the "right ear." P1's wife further stated that she was present during the biopsy and that the site was the top of the left inner ear. D. During interview on 03/04/19 at 10:00 am, the Assistant Regional Manager stated that her investigation of the incident indicated that MA1 did not follow policy and perform a "safety check" during the patient visit on 01/31/19. According to the Assistant Regional Manager, any staff member entering a patient exam room should ask the patient the purpose of the visit, including the location of any areas of concern. She further stated that the laboratory director was not notified when the error was identified. E. Review of the laboratory's policy, "The Results Log-Notification Standards, Communication, and Documentation Policy" dated 03/23/18 indicated: "Providers are responsible for reviewing the clinical pathology reports for all their patients, ensuring an accurate diagnosis is entered.." F. Review of the laboratory's policy, "Safety Pause - Specimens" dated 04/16/18 indicated: 1. "The time Out is a deliberate pause in activity involving clear communication ... among all members of the surgical/procedural team... The Time Out includes verifying: a. Correct patient identity b. Correct procedure verified with consent. c. Correct site" 2. "Specimen Jars are to be labeled prior to the procedure."
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and interview with the laboratory director, the laboratory director failed to review and approve the laboratory's policies. Findings are: A. Review of the laboratory's policy, "The Results Log-Notification Standards, Communication, and Documentation Policy" dated 03/23/18 and "Safety Pause - Specimens" dated 04/16/18 indicated no documentation that the laboratory director had reviewed and approved the policies. The policy only stated that it was approved by "Medical Directors" without identifying the approvers. B. During interview on 03 /04/19 at 11:00 am, the laboratory director stated that she did not have oversight responsibility of office operations. Her only area of responsibility was the Moh's surgery (a procedure to remove difficult to treat skin cancers) performed one day per week.