

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2174856	<b>(X3) Date Survey Completed</b>  10/19/2023
<b>Name of Provider or Supplier</b>  Epiphany Dermatology, Pa	<b>Street Address, City, State</b>  616 E Bailey Boswell Rd, Saginaw, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicaid &amp; Medicare Services) 116 form, laboratory policy, laboratory proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology (MOHS) slide interpretations at least twice annually for 1 of 2 testing events in 2022. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (MOHS) procedures. 2. Review of the laboratory policy titled "Laboratory: Microscopic Interpretation, Quality Assessment; Proficiency Testing" revealed: "PROCEDURE ... 2. Proficiency shall be assessed at least semiannually. 3. Proficiency for Epiphany Dermatology Mohs Surgeons shall be assessed using one of the following methods. The Laboratory Director shall choose and implement whichever option works best for their particular laboratory. Laboratories will be required to pay for External Quality Control. Internal Peer Review and Epiphany Dermatology Company Peer Review are provided at no cost to the Mohs laboratories." 3. Review of the laboratory's proficiency testing for 2022 revealed PT was performed once in 2022. The laboratory was asked to provide documentation of a second event in 2022 and none was provided. The laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations in 2022. 4. During an interview on 10/19/2023 at 2:53 pm, the Compliance Officer confirmed the above findings.</p>

**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 laboratory policy, laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure 1 of 5 patient KOH (potassium hydroxide) preparation results were transcribed accurately to the final test report in 2023 (random review August 2023 through September 2023). Findings included: 1. Review of the laboratory's policy titled "KOH Protocol" revealed: "RESULTS: There should be no air bubbles under the coverslip that might obscure the dermatophytes. A correctly prepared slide will allow the physician and/or mid-level provider to render a fast and correct diagnosis of a specimen. A normal, or negative, KOH test shows no evidence of fungi. Dermatophytes or yeast seen on a KOH test indicate that the person has a fungal infection. Fungi causing ringworm infections produce septate (segmented) hyphae, or long branch-like tubular structures. Yeast cells appear round and oval. Budding forms may be seen. KOH cannot identify the specific organism. If necessary, a biopsy can be procured and submitted for permanent pathologic processing, or a second scraping may be taken and submitted for culture." 2. Review of the laboratory's "Mycology Log" and corresponding patient final reports revealed the following: 09/28/2023 MRN: MM0002674462 Mycology Log: "-" Final report: "Examination of the slide showed: fungal hyphal elements: positive" The laboratory failed to accurately transcribe results of KOH preparations to the final reports. 3. During an interview on 10/19/2023 at 2:33 pm, the Compliance Officer confirmed the above findings.