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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D2098645 | <b>(X3) Date Survey Completed</b><br><br>06/19/2023 |
| <b>Name of Provider or Supplier</b><br><br>Epiphany Dermatology, Pa  | <b>Street Address, City, State</b><br><br>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. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <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>D5801</b>              | <p>TEST REPORT<br/>CFR(s): 493.1291(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy, laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure 2 of 7 patient KOH (potassium hydroxide) preparation results were transcribed accurately to the final test report in 2022 (random review February 2022 through December 2022). The findings include:<br/>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."</p> |

2. Review of the laboratory's "Mycology Log" and corresponding patient final reports revealed the following: 06/29/2022 MRN: MM0001240421 Mycology Log: "Positive (+)" Final report: "Examination of the slide showed: branching hyphae" 08/18/2022 MRN: MM0001002797 Mycology Log: "Positive (+)" Final report: "Examination of the slide showed: branching hyphae" The laboratory failed to accurately transcribe results of KOH preparations to the final reports. 2. During an interview on 06/19/2023 at 9:55 a.m., the Clinical Operations Manager and Quality Compliance Specialists confirmed the above findings.