

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0722853	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Epiphany Dermatology, Pa	Street Address, City, State 1615 Hospital Parkway Suite 306, Bedford, 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 found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5801	<p>TEST REPORT 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: Based on review of laboratory policy, laboratory records, patient records, and confirmed in interview, the laboratory failed to ensure 1 of 6 patient KOH (potassium hydroxide) preparation results were transcribed accurately to the final test report in 2022 (random review September 2022 through April 2023). The findings include: 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</p>

of the laboratory's "Mycology Log" and corresponding patient final reports revealed the following: 12/15/2022 MRN: MM0002499334 Mycology Log: "(+)" Final report: "Examination of the slide showed: +/- results" The laboratory failed to accurately transcribe results of KOH preparations to the final reports. 2. During an interview on 05/16/2023 at 10:34 a.m., the Office Manager confirmed the above findings.