

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0928636	<b>(X3) Date Survey Completed</b> 06/27/2023
<b>Name of Provider or Supplier</b> Epiphany Dermatology, Pa	<b>Street Address, City, State</b> 911 Lamar Avenue, Paris, 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>	An onsite survey conducted 06/27/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, laboratory testing records, and confirmed in an interview, the laboratory failed to document microscope maintenance for two of two microscopes in use from September 2022 through May 2023. The findings included: 1. During a tour of the laboratory on 6/27/2023 at 12:00 hours the surveyor observed the following two microscopes used in patient testing: Olympus BX41 Olympus BX46 2. Review of the laboratory policy titled "Microscope Use Protocol", section "procedure" had the following instructions: "Procedure: 1. The microscope stage and ocular pieces are to be cleaned weekly. The stage is cleaned using alcohol or a similar cleaner and the ocular eyepieces are cleaned with lens paper. 2. The grounding check is monitored every six months. 3. The ocular micrometer is fixed so it does not need calibration. 4. Notify the supervisor if any problems occur with the instrumentation. 5. Preventative maintenance must be performed on each piece of equipment annually by a qualified technician. 6. Every action is documented on the maintenance record form." Surveyor queried for the maintenance record form for the two microscopes for September 2022 to May 2023 and non were provided. 3. Review of testing logs from September 2022 through May 2023 had 232 patients with microscopic testing performed to include the following random 10 patients: September 19th, 2022: 2 patients tested (see patient crosswalk)</p>

October 31st, 2022: 2 patients tested (see patient crosswalk) November 14, 2022: M0002311869 December 22, 2022: 2 patients tested (see patient crosswalk) March 13th, 2023: 2 patients tested (see patient crosswalk) May 11, 2023: 1 patient tested (see patient crosswalk) 4. In an interview on 6/27/2023 at 12:10 hours, in the facility, the Clinical Operations Manager confirmed that the maintenance forms had not been completed for the two microscopes in use for patient testing.