

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2142580	<b>(X3) Date Survey Completed</b>  03/16/2021
<b>Name of Provider or Supplier</b>  Epiphany Dermatology Of Missouri, Llc	<b>Street Address, City, State</b>  805 N 36th St, Ste D, Saint Joseph, MO	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 proficiency records for 2019, 2020 and interview with the medical receptionist, the laboratory failed to establish a means to verify the accuracy of potassium hydroxide (KOH) microscopic testing twice a year. Findings: 1. Review of proficiency records for 2019 and 2020 revealed the laboratory failed to prove accuracy on the nonregulated analyte for KOH microscopic exams twice yearly. 2. Interview with the medical receptionist on March 16, 2021 at 12:15 PM confirmed the laboratory failed to verify the accuracy of the nonregulated KOH microscopic testing twice annually.</p>
<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 lack of histopathology procedures, potassium hydroxide (KOH) microscopic procedures, manual hematoxylin staining procedure, eosin staining procedure, and interview with medical receptionist, the laboratory failed to provide written procedures for testing personnel. Findings: 1. Review of procedures showed no</p>

	<p>procedures for histopathology, potassium hydroxide (KOH) microscopic, manual hematoxylin staining, and eosin staining. 2. Interview with medical receptionist on March 16, 2021 at 12:30 PM confirmed the laboratory could not provide written procedures for histopathology, potassium hydroxide (KOH) microscopic, manual hematoxylin staining, and eosin staining.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of histopathology marking dyes, and interview with medical receptionist, the laboratory failed to discard expired marking dyes. Findings: 1. Observation of histopathology marking dyes showed: Green tissue marking dye lot # 068619, expiration date August 1, 2020 still in use. Red tissue marking dye lot # 068471, expiration date August 1, 2020 still in use. Blue tissue marking dye lot # 068467, expiration date August 1, 2020 still in use. Black tissue marking dye lot # 067444, expiration date June 2020 still in use. 2. Interview with medical receptionist on March 16, 2021 at 12:15 PM confirmed the laboratory failed to discard expired marking dyes</p>
<p><b>D5433</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation for 2019/2020 maintenance and interview with medical receptionist the laboratory failed to document maintenance for microscope, cryostat, and Avantik airflow. Findings: 1. Review of microscope showed no documentation for microscope maintenance in 2019 and 2020. 2. Review of Lecia CM1850 cryostat showed no documentation for cryostat maintenance in 2019 and 2020. 3. Review of Avantik airflow showed no documentation for airflow maintenance in 2019 and 2020. 4. Interview with medical receptionist on March 16, 2021 at 12:30 PM confirmed that the laboratory failed to document maintenance in 2019 and 2020.</p>