

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2117332	(X3) Date Survey Completed 02/13/2025
Name of Provider or Supplier Empire Dermatology Pllc	Street Address, City, State 5823 Widewaters Parkway, Suite 10, E Syracuse, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), competency assessment records, as well as interviews with the Testing Person (TP) and the Office Manager (OM), the laboratory failed to perform and document competency assessments. FINDINGS: 1. There was no documentation of competency assessment performance for the Laboratory Director (LD), Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS), and Testing Personnel responsible for performing PPMP. 2. This was contrary to instructions included in the current, approved SOPs. 3. The TP and OM confirmed the findings on February 13, 2025, at 3:30 P.M.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory systems Quality Assurance (QA) procedures, QA records, as well as interviews with the TP and the OM, the laboratory failed to</p>

	<p>perform and document QA. FINDINGS: 1. There was no documentation of QA records for years 2023 and 2024. 2. This was contrary to instructions indicated in the current, approved QA Plan. 3. The TP and OM confirmed the findings on February 13, 2025, at approximately 3:10 P.M.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of SOPs, as well as interview with the TP, the laboratory failed to properly identify the reagent, concentration, lot number, expiration date, and storage requirements for the solution/reagent positions located on the automated stainer in the Mohs processing lab. FINDINGS: a. The surveyor's observations in the Mohs processing laboratory on February 13, 2025, at approximately 11:30 A.M. confirmed the following reagents located on the Thermo Scientific Linistain automated stainer, SN: LS5024A1609, in the Mohs laboratory, were not labeled with identification, concentration, lot number, expiration date, and storage requirements: 1. 95% Alcohol 2. Water 3. Hematoxylin 4. 0.1% Acid Alcohol Solution 5. Eosin Y 6. 100% Alcohol 7. Xylene substitute b. The current, approved SOPs did not include instructions for performing such activity. c. The TP confirmed the findings on February 13, 2025, at approximately 3:00 P.M.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, competency assessment records, as well as interviews with TP and the OM, the LD failed to perform and document personnel competency assessment performance as well as comply with instructions included in the current, approved SOPs. Refer to D5209.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required</p>

for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of SOPs, laboratory policies, as well as interviews with the TP and the OM, the laboratory failed to draft, approve written responsibilities and duties for each person involved in all phases of testing. FINDINGS: 1. The current, approved SOPs and laboratory policies did not include documentation of LD, CC, TS, GS, and TP job descriptions. 2. The TP and OM confirmed the findings on February 13, 2025, at 3:30 P.M.