

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2117332	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Empire Dermatology Plc	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
D5217	<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 surveyor's review of the twice year verification procedure, twice year verification for the Mohs slides, and an interview with the Mohs technician, the laboratory failed to verify the accuracy of interpretation of the KOH at least twice per year for calendar year 2017. FINDINGS: The Mohs technician confirmed on September 26, 2018 at approximately 9:30 AM, the surveyor's findings that the laboratory failed to verify the accuracy of the KOH slides for the calendar year 2017. Approximately 92 patients' KOH slides were interpreted and reported in calendar year 2017.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS 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:</p>

Based on surveyor's review of the Mohs procedure manual, cryostat service and preventative maintenance records and an interview with the Mohs technician, the laboratory failed to document the daily and as needed maintenance, as indicated by the cryostat maintenance procedure.