

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2083635	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Illinois Dermatology Institute	Street Address, City, State 25 E Washington St Suite #1221, Chicago, IL	
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
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the office manager (OM), the laboratory failed to monitor and evaluate the overall quality for histopathology and mycology testing at least twice a year in 2021 and 2022. (Refer to D5217).</p>
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 on review of laboratory records, lack of documentation, and interview with the office manager (OM), the laboratory failed to evaluate the biannual method accuracy for histopathology and mycology testing at least twice a year in 2021 and 2022. Findings include: 1. Review of the "Mohs / Histology Laboratory Compliance Manual" page #53 (Laboratory Director) revealed: a. "4. Ensure that the laboratory is enrolled in a HCFA - approved proficiency testing program." b. "5. Ensure that the</p>

quality control and quality assurance programs are established and maintained to assure the quality of the laboratory services provided and to identify failures in quality as they occur." 2. Review of laboratory records and lack of documentation revealed that the laboratory failed to evaluate and document the biannual method accuracy for histopathology testing in 2021 and 2022. Affecting a total of 256 Mohs procedures: a. Annual Mohs procedures (2021) = 86 b. Annual Mohs procedures (2022) = 170 3. Review of laboratory records and lack of documentation revealed that the laboratory failed to evaluate and document the biannual method accuracy for potassium hydroxide (KOH) testing in 2021 and 2022. Affecting a total of 89 test results: c. Annual KOH testing volume (2021) = 29 d. Annual KOH testing volume (2022) = 60 4. On 05/11/2023 at 11:10 a.m., the OM stated, "The laboratory failed to enroll in proficiency testing for KOH and did not have records for the histopathology biannual method accuracy for 2021 and 2022."