

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1071032	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier Illinois Dermatology Institute Llc	Street Address, City, State 1550 N Northwest Hwy, Ste 300, Park Ridge, 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 records review, Plan of Correction received on 04/29/2019, and interview with the laboratory manager, the laboratory failed to properly manage and evaluate the overall quality of testing. The laboratory must meet the requirements in 493.1231 through 493.1236. Findings include: REPEAT DEFICIENCY 1. The laboratory failed to verify the accuracy of the Mycology identification test it performs in the laboratory, at least bi-annually. See 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: REPEAT DEFICIENCY Based on records review, lack of documentation, Plan of Correction (POC) received on 04/29/2019, and interview with the laboratory manager; the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH) procedure it performs at least twice annually, during the years of 2019 through 2021.</p>

Findings: 1. The laboratory's policies and procedures, proficiency testing records, and patients test records were reviewed. 2. The manual and test records revealed the laboratory performed KOH preparations (Preps) for fungal identification and participated in the American Proficiency Institute (API) proficiency testing (PT) program to verify the accuracy of their KOH procedure. 3. The API-PT documents showed the laboratory's last participation event was Event #3 of 2018. 4. The laboratory failed to establish another method to verify the accuracy of its KOH procedures when they did not re-enroll in the API-PT program during the years of 2019 through 2021. 5. The laboratory failed to implement the POC it submitted on 04/29/2019 to ensure its KOH procedure to identify fungal organisms was accurate. 6. On a Recertification survey conducted on 07/21/2021 at 11:30 AM, the laboratory manager confirmed the past citation of this deficiency and above findings.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review, the Laboratory Personnel Report (CMS 209), and interview with the laboratory manager; the technical consultant (TC) failed to assess the test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples of all testing personnel performing mycology testing, affecting 5 out of 5 testing personnel (TP). Findings: 1. The laboratory manuals, the CMS 209, and personnel files from the years of 2019 through 2021 were reviewed. 2. The CMS 209 list 5 TP (TP2, TP3, TP5, TP9 and TP10) performing Potassium Hydroxide (KOH) preparations in the laboratory. 3. The KOH competency procedures and employee records revealed the following: *The TP was given 1 (one) slide to perform the KOH procedures and fungal identification as competency. *The test slide given to 4 out of 5 TP were "negative" or no fungal organism present slides. *Only 1 out of 5 TP was given a "Positive" (actual slide with fungal organism present) for identification during the years of 2019 through 2021. 4. The TC failed to include actual fungal organisms or "positive" slides in the assessment of each TP performing KOH preparations to accurately assess their ability to identify fungal organisms. 5. On a Recertification survey conducted on 07/21/2021 at 11:30 AM, the laboratory manager confirmed the above findings.