

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1066591	(X3) Date Survey Completed 02/28/2022
Name of Provider or Supplier Dermatology & Aesthetics Of Wicker Park	Street Address, City, State 1765 N Elston Ave, Ste 110, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documents, and interview, the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH) procedure it performs, affecting 110 patients' tests. Findings include: 1. The American Proficiency Institute (API) proficiency testing (PT) program records for 2020 and 2021, KOH patient test log, and procedures manual were reviewed. 2. The manual stated the laboratory would enroll in API's "Microscopy - KOH Preparation, (glass slide)" PT program as the method to verify the accuracy of its KOH procedure. 3. The API-PT reports revealed the laboratory received the following scores: EVENT SCORE 2020 1st 100% 2020 2nd Failure to Participate 2020 3rd 0% - Unsatisfactory Performance 2021 1st 0% - Unsatisfactory Performance 2021 2nd 50% - Unsuccessful 2021 3rd 50% - Unsuccessful 4. Further review of the documents showed the laboratory investigated one (Event 2021 3rd) out of five PT failed events. The laboratory failed to provide any other documentation that verified the accuracy of its KOH procedures when receiving continuous failures. 5. Review of the patients' KOH logs from 02/2020 to 02/2021 revealed 110 patients were tested and reported. 6. On a Recertification survey conducted on 02/28/2022 at 12:50 PM, office staff and laboratory manager confirmed the above findings.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure the appropriate staff evaluated the laboratory's performance and identified any problems that require corrective action, during the years of 2020 and 2021. Findings: 1. The American Proficiency Institute (API) proficiency testing (PT) program records for 2020 and 2021 and procedures manual were reviewed. 2. The PT documents revealed the laboratory failed five out of six PT events during the period reviewed. See D5211. 3. Further review showed the laboratory failed to provide any documented evidence of PT failure investigation and any corrective actions taken, if necessary. 4. The LD failed to ensure the PT policies and procedures were followed by staff. 5. On a Recertification survey conducted on 02/28/2022 at 12:50 PM, office staff and laboratory manager confirmed the above findings.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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;

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure testing personnel (TP) were competent to perform Potassium Hydroxide (KOH) procedures and identify training needs when necessary for six out of six TP. Findings: 1. The Laboratory Personnel Report (CMS-209), employee files, and proficiency testing (PT) program documents for the years of 2020 and 2021 were reviewed. 2. The CMS-209 listed six TP who performed microscopic KOH procedures in the laboratory. 3. The PT documents showed that the laboratory received failure scores for five out of six PT events during the period reviewed. See D5211. 4. The LD failed to ensure the PT failures were investigated to identify the possible need for retraining of the TP who participated in the events. 5. On a Recertification survey conducted on 02/28/2022 at 12:50 PM, office staff and laboratory manager confirmed the above findings.