

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2093482	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Medical Dermatology Associates Of Chicago	Street Address, City, State 363 W Erie St, Suite 250, 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
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: REPEAT DEFICIENCY Based on record review, the Laboratory Personnel Report (CMS 209), previous Plan of Corrections (POC), and an interview with the office staff; the laboratory failed to follow written procedures to assess employees performing Potassium Oxide (KOH) testing, affecting 4 out of 4 testing personnel (TP). Findings: 1. The CMS 209, personnel records, procedures manual, and 04/08 //2019 Plan of Correction (POC) were reviewed. 2. The laboratory submitted as a POC, a written policy and procedure to assess the competency of it's TP performing KOH microscopic procedures on 04/08/2019. 3. The laboratory failed to follow the written competency procedure and evaluate the TP (TP1, TP2, TP3, and TP4) listed on the CMS 209 as employees performing KOH procedures. 4. The personnel records revealed the last documented competency evaluation for TP1, TP2, TP3 and TP4 was dated 03/25/2019. 5. On a Recertification survey conducted on 12/15/2020 at 3:30 PM, the office staff confirmed the above findings.</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:</p>

Based on record review, lack of documents, and an interview with the office staff, the laboratory failed to verify the accuracy of the Potassium Oxide (KOH) procedure it performs, affecting 20 patients. Findings include: 1. The College of American Pathologists (CAP) proficiency testing (PT) program records, KOH patient test log and reports, and procedures manual were reviewed. 2. The CAP email confirmation showed the laboratory had enrolled into their "Clinical Microscopy" program as the method to verify the accuracy of its KOH procedure on 03/27/2019. 3. Further review revealed no documentation of participation during the year of 2019, after enrollment, through 2020. 4. Review of patients test records from 04/11/2019 to 08/19/2020 revealed 20 patients were tested and reported. 5. The laboratory failed to establish another method to verify the accuracy of its KOH procedures when they did not participate in the CAP-PT program. 6. On a Recertification survey conducted on 12/15/2020 at 3:30 PM, the office staff confirmed the above findings.