

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2093482	<b>(X3) Date Survey Completed</b> 03/07/2019
<b>Name of Provider or Supplier</b> Medical Dermatology Associates Of Chicago	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Based on the laboratory's procedures, records, the Laboratory Personnel Report (CMS 209), and an interview with the office staff; the laboratory failed to establish 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, and procedures manual were reviewed. 2. The laboratory failed to have a written competency procedure to evaluate it's TP performing KOH testing. 3. TP1, TP2, TP3, and TP4 were listed on the CMS 209 for performing KOH testing. 4. The personnel documents for TP1, TP2, TP3 and TP4 did not include a KOH performance evaluation . 5. On an Initial survey conducted on 03/07/19 at 11:50 AM, the office staff confirmed the above findings.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:  
Based on the Laboratory Personnel Report (CMS 209), the laboratory's procedures, records, and an interview with the office staff; the laboratory director (LD) failed to ensure that prior to testing patients' specimens, all personnel have appropriate training for the Potassium Oxide (KOH) testing performed, and have demonstrated that they can perform the testing reliably to provide and report accurate results, affecting 4 out of 4 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and the procedures manual were reviewed. 2. TP1, TP2, TP3, and TP4 are licensed physicians approved to perform KOH testing. a). The LD fail to have an establish written procedure available for the TP; b). The 4 TP had not received training to perform the KOH test; and c). The LD failed to assess the competency of the 4 TP to perform the KOH test, prior to testing patients. 3. On an Initial survey conducted on 03/07/19 at 11:50 AM, the office staff confirmed the above findings.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:  
Based on the laboratory's procedures manual, records, and an interview with the office staff; the laboratory director (LD) failed to ensure that an approved procedure manual is available to personnel responsible for the Potassium Oxide (KOH) testing in the laboratory, affecting 4 out of 4 testing personnel (TP). Findings: 1. The Laboratory Personnel Report (CMS 209), personnel records, and the procedures manual were reviewed. 2. The LD fail to establish a written procedure for the laboratory's KOH testing. 3. TP1, TP2, TP3, and TP4 are licensed physicians approved to perform KOH testing. 4. On an Initial survey conducted on 03/07/19 at 11:50 AM, the office staff confirmed the above findings.