

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0962525	<b>(X3) Date Survey Completed</b>  05/15/2024
<b>Name of Provider or Supplier</b>  Dermatology Center, PLLC	<b>Street Address, City, State</b>  7900 Dallas Street, Fort Smith, AR	
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: A review of the laboratory's policy and procedure for "QA for KOH testing Addendum", documents for "laboratory personnel competency" and interview determined that the laboratory failed to document laboratory personnel competency on an annual basis for three of five laboratory personnel who perform KOH examinations. Findings follow: A) Review of the laboratory's policy and procedure for "QA for KOH Testing Addendum" revealed "the Dermatology Center will do annual quality assurance KOH testing between physicians in the clinic. Quality Assurance testing was not performed in 2011 or 2012. Action was taken on January 2014 to assure annual QA testing will occur". B) Review of "Laboratory Personnel Competency" forms revealed that KOH competency was documented for laboratory personnel #1 (as listed on a separate laboratory staff list) on 3/15/18, 12/31/19, and 8/9/22. C) Review of "Laboratory Personnel Competency" forms revealed that KOH competency was documented for laboratory personnel #2 (as listed on a separate laboratory staff list) on 1/3/20, and 8/9/22. D) Review of "Laboratory Personnel Competency" forms revealed that KOH competency was documented for laboratory personnel #3 (as listed on a separate laboratory staff list) on 8/9/22. E) Upon request, the laboratory was unable to provide documentation for performing KOH competency for the personnel identified above for 2021, 2023 and 2024. F) In an interview at 02:55 p.m. on 5/15/24, laboratory staff (#1 as listed on the form CMS-209) confirmed that KOH competency was not performed on the personnel identified above and the personnel performed KOH testing during calendar years 2021, 2023 and 2024.</p>

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

A review of the Mohs Surgery Logs for January through April 2024, a review of Temperature Monitor Logs for January through April 2024 and interviews with laboratory staff, determined the laboratory failed to document cryostat temperatures on one of sixty-four days when Mohs surgery was performed in 2024. Survey findings include: A) A review of the Mohs Surgery logs for April 2024 documented the laboratory performed Mohs Surgery on 4/15/24 ( 7 patients),. B) A review of the Temperature Monitor Logs 2024 ( January through April), revealed the laboratory failed to document cryostat temperatures on 4/15/24 (7 patients tested), C) In an interview at 02:55 p.m. on 5/15/24, laboratory staff (#1 as listed on the form CMS-209) confirmed that the cryostat temperature was not documented on 4/15/24 and Mohs surgery was performed on that day.