

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2135677	<b>(X3) Date Survey Completed</b> 01/14/2020
<b>Name of Provider or Supplier</b> Advanced Dermatology Of Pennsylvania	<b>Street Address, City, State</b> 107 Gamma Drive, Ste 120, Pittsburgh, PA	
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 review of the laboratory's competency assessment for testing personnel procedure and interview with the regional vice president and the office manager, the laboratory failed to assess the competency of 2 of 2 testing personnel (TP) who performed KOH and wet mount microscopic procedures from 2018 to the day of survey. Findings Include: 1. The Competency Assessment for Testing Personnel procedure, 4. Policy states, " Laboratories that perform moderate to high complexity testing participate in competency assessment of all testing personnel that include six procedures". 2. On the day of survey, 01/14/2020, the laboratory could not provide competency assessment documentation for 2 of 2 TP who performed KOH and Wet mounts from 07/017/2018 to 01/14/2020. 3. The regional vice president and the office manager confirmed the findings on 11/14/2020 around 9:30 am. ***KOH = Potassium Hydroxide</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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: Based on review of peer review records and interview with the regional vice president</p>

and the office manager, the laboratory failed perform at least twice annually the accuracy of KOH and Wet prep microscopic examination procedures in 2018 and 2019. Findings Include: 1. On the day of survey, 01/14/2020, review of peer review records revealed, the laboratory did not perform at least twice annually the accuracy of KOH and Wet preps examination procedures in 2018 and 2019. 2. The regional vice president and the office manager confirmed the above findings on 01/14/2020 around 9:45 am. \*\*\*KOH = Potassium Hydroxide

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory room temperature thermometer, interview the regional vice president and the office manager, the laboratory failed to perform maintenance/ calibration on 1 of 1 fisher scientific traceable thermometer in 2019. Findings Include: 1. On the date of survey, 01/14/2020, while on tour of the laboratory, 1 of 1 fisher scientific traceable thermometer (S/N: 170600121) observed in use to monitor the room temperature of the laboratory, was due for maintenance/ calibration on 08/22/2019. 2. The regional vice president and the office manager confirmed the above findings on 01/14/2020 around 10:50 am.