

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0885383	(X3) Date Survey Completed 08/02/2023
Name of Provider or Supplier Aesthetic Dermatology Associates Pc	Street Address, City, State 176 S New Middletown Road, Suite 203, Media, PA	
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: Based on CLIA competency assessment record review and interview with the Registered Nurse (RN), the laboratory failed to perform the annual competency assessment of 1 of 3 Clinical Consultants (CC), 1 of 3 Technical Supervisor (TS), 1 of 3 General Supervisor (GS) and 1 of 9 Testing personnel (TP) for their supervisory and testing responsibilities for the histopathology section in 2021 and 2022. Findings Include: 1. On the day of the survey 08/02/2023 at 12:00 PM the laboratory could not provide 2021 and 2022 annual competency assessments for 1 of 3 CC (CMS-209). 2. The laboratory could not provide 2021 and 2022 annual competency assessments for 1 of 3 GS (CMS 209) for the histopathology slide review. 3. The laboratory could not provide 2021 and 2022 annual competency assessments for 1 of 3 TS (CMS 209, TP#7) for the histopathology slide review, parasitology, and mycology testing. 4. The laboratory could not provide 2021 and 2022 annual competency assessments for 1 of 9 TP (CMS 209) for the histopathology slide review. 5. The RN confirmed the above findings on 08/02/2023 around 01:30 PM.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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 establish a maintenance protocol that ensures equipment, instrument, and test system</p>

performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, and an interview with Registered Nurse (RN), the laboratory failed to establish a maintenance protocol that ensures equipment performance for 1 of 1 thermometer used for Room Temperature (RT) and Humidity monitoring for the Histopathology testing from 7/27/2021 to the day of the survey.

Findings include: 1. At the time of the survey, on 08/02/2023 at 12:30 PM, an observation of the laboratory revealed that the laboratory failed to document calibration activities for the following instruments. - Enviracaire Thermometer. 2. The laboratory failed to provide a calibration protocol for the accuracy of the thermometer listed above. 3. According to Laboratory's Room humidity policy and Room Temperature Policy for Mohs lab, the temperature should be between 60-73 degrees and the humidity should be 0-60% in the laboratory. 4. RN confirmed the findings above on 08/02/2023 at 01:30 PM.