

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2142589	(X3) Date Survey Completed 12/11/2019
Name of Provider or Supplier Aesthetic Dermatology Associates, Pc -Paoli Office	Street Address, City, State 4 Industrial Blvd, Suite 200, Paoli, 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 laboratory procedure manual review and interview with the Registered Nurse (RN), the laboratory failed to establish a competency assessment policy to assess 1 of 2 clinical consultant (CC)/ technical supervisor (TS) from 2018 to the day of survey. Findings Include: 1. On the day of survey,12/11/2019, the laboratory could not provide a competency assessment policy to assess 1 of 2 CC/ TS in 2018 and 2019. 2. The laboratory could not provide documentation of assessed competency for 1 of 2 CC/TS from 05/14/2018 to 12/11/2019. 3. The RN confirmed the findings above on 12/11/2019 around 8:05 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory refrigerator thermometer and interview a registered nurse (RN), the laboratory failed perform maintenance/ calibration on 1 of 1 fisher scientific traceable thermometer in 2019. Findings Include: 1. On the date of survey, 12/11/2019, while on tour of the laboratory, 1 of 1 fisher scientific traceable</p>

thermometer (S/N: 170702549) observed, was due for maintenance/ calibration on 10 /02/2019. 2. The RN confirmed the finding above on 12/11/2019 around 8:30 am.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on Mohs, KOH and Scabies final test reports and interview with the Registered Nurse (RN), the laboratory failed to indicate on patient final test reports (3 of 3 reviewed), the correct address where tests were performed in 2018 to the day of survey. Findings Include: 1. On the day of survey, 12/11/2019, review of patient Mohs, KOH and scabies final reports (3 of 3 reviewed) revealed the final test reports did not include correct address where patient tests were performed. 2. The final reports stated "176 S New Middletown Rd #203, Media, PA 19063, when patient tests were performed at "21 Industrial Blvd suite 101, Paoli, PA 1930." 3. The RN confirmed on 12/11/2019 around 8:40 am, that patient test reports did include the laboratory's name but did not indicate the correct address where patient tests were performed. Note: KOH= Potassium Hydroxide