

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0885383	(X3) Date Survey Completed 02/26/2019
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 surveyor review of procedure manual and interview with the Registered Nurse (RN), the laboratory failed to establish and follow written procedures to assess 2 of 3 Mohs Testing Personnel (TP) competency which is required under subpart M in 2017 to the date of survey. Findings Include: 1. On the day of survey, 02/26/2019, the laboratory could not produce a written procedure for the competency assessment for the Mohs TP. 2. The laboratory could not provide documentation of assessed competency for 2 of 3 TP (TP#4 and TP#6) from 2017 to 2018. 3. The RN confirmed the finding above on 02/26/2019 around 9:30 am.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 laboratory records and interview with the Registered Nurse (RN), the laboratory failed to verify the accuracy of the microscopic examination for histopathology (Mohs macroscopic surgery) at least twice annually during 2018 as required for tests not included in subpart I. Finding Include: 1. On the day of survey, 02/26/2019, review of Mohs proficiency testing records revealed that in 2018 peer</p>

review slides were pulled for review on 12/17/2018, peer review was not performed twice. 2. The RN confirmed the findings above on 02/26/2018 around 10:00 am.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of reagents and interview with the Registered Nurse (RN), the laboratory failed to label The Davidson Marking systems, Tissues marking dye Bottles (5 of 5) and The National Diagnostics Histo- Clear 1, Gallon Bottles (4 of 4) with expiration dates at the time of survey. Finding Include: 1. On the day of survey, the following reagents were observed with out expiration dates: a. The Davidson Marking systems, Marking dye Bottles: - 1 of 1 bottle of Blue Lot# 557-515160. - 1 of 1 bottle of Red Lot# 425-511201. - 1 of 1 bottle of Yellow Lot# 229-525290. - 1 of 1 bottle of Green Lot# 133-718220. - 1 of 1 bottle of Black Lot# 322-512240. b. The National Diagnostics Histo- Clear, Clearing Agent, 1 gallon Bottles: - 1 of 1 bottle, Lot# 04-18-24. - 3 of 3 bottles, Lot# 12-18-28. 2. The RN confirmed the findings above on 02/26/2019 around 11:15 am.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Cryostat temperature logs and interview with the Registered Nurse (RN), the laboratory failed to document corrective actions taken when the Cryostat temperature readings exceeded the acceptable ranges from August 11th, 2017 to February 26th, 2019 (23 of 55 days of patient tests reviewed). Findings include: 1. On the day of survey, 02/26/2019, review of the Tissue Pathology Cryostat Temperatures logs revealed, the acceptable temperature range (-21 to -26 degrees Celsius), was exceeded: a. 3 of 18 days of patient testing from August, 2017 to December, 2017. b. 18 of 32 days of patient testing from January, 2018 to December 2018. c. 3 of 10 days of patient testing from January, 2019 to February 2019 . 2. On February 26th, 2019 around 10:30 am, the RN confirmed the laboratory did not document the corrective action taken for exceeded cryostat temperatures from August 2017 to February 2019.

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 reports (4 of 4 reviewed), the address of the laboratory location where tests were performed. Findings Include: 1. On the day of survey, 02/26/2019, review of patient Mohs, KOH and scabies final reports (4 of 4 reviewed) revealed the reports did not include the address of the laboratory's location. 2. The site is 1 of 2 laboratory locations with the same name but with different addresses. 3. The RN confirmed on 02/26/2019 around 10:30 am, that patient test reports did include the laboratory's name but did not indicate the address of the laboratory's location, where testing was performed. Note: KOH= Potassium Hydroxide