

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2001790	(X3) Date Survey Completed 11/21/2019
Name of Provider or Supplier Aesthetic Dermatology, Llc	Street Address, City, State 771 Route 70 E, Marlton, NJ	
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
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 the lack of a Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Histopathology testing twice annually in the calendar years 2018 and 2019. The OM confirmed on 11/21/19 at 11:50 am the laboratory did not perform BA twice annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, the Microscope daily maintenance log, observation of the microscope and interview with the Office Manager (OM), the laboratory failed to follow Microscope Maintenance Procedure (MMP) in the calendar year 2019. The finding includes: 1. The PM stated to clean microscope at the end of each day of testing but there was no documentation of maintenance performed in the calendar year 2019. 2. The OM confirmed on 11/21/19 at 10:00 am that the laboratory did not follow MMP.</p>

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Patient Manifest (PM) included with Histopathology slides, and interview with the Office Manager (OM), the laboratory failed to maintain an accurate information system for Histopathology slides from 11/28/17 to the date of the survey. The findings include: 1. Review of a PM received from a laboratory did not list the number of slides received for each patient. 2. The OM confirmed on 11/21/19 at 11:25 am that the laboratory did not maintain an accurate information system.