

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1099367	<b>(X3) Date Survey Completed</b>  09/20/2021
<b>Name of Provider or Supplier</b>  Aesthetic Dermatology Pc	<b>Street Address, City, State</b>  960 Sanders Road Suite 300, Cumming, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 20, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) policy and interview with laboratory director, the laboratory failed to have an adequate (QA) policy to assess, evaluate, monitor and correct problems in the laboratory as required by CLIA. The findings include: 1. Review of QA records revealed the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems. QA activities were not documented in the laboratory to reflect all phases of the QA policy (Pre analytic, Analytic and Post Analytic phases) in 2020 and 2021. 2. An interview with the laboratory director on 09/20/2021 at approximately 3:30 PM in the break room confirmed that the laboratory was not documenting QA activities in 2020 and 2021.</p>
<b>D5447</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on Quality Control (QC) document review and laboratory director interview, the laboratory failed to perform and document QC as described in the QC manual on Dermatophyte Test Medium (DTM) in 2020 and 2021. Findings include: 1. Based on review of QC manual and documents review, a known positive, negative and sterile controls were to be performed at least with any new batch of DTM shipment and during patient testing. Instead, the clinic used a previous positive and an empty plate as negative controls in 2020 and 2021. 2. There was NO Individualized Quality Control Plan (IQCP) established by the laboratory. 3. During an interview with the lab director on 09/20/2021 at approximately 3:00 PM in the review room, it was confirmed that QC was not performed as recommended by QC procedure manual on DTM testing in 2020 and 2021.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on patient reports review and interview with the laboratory director, the laboratory failed to provide the units of measure and reference ranges on patient's DTM final results reports in 2020 and 2021. Findings include: 1. Review of patient reports revealed they did not have units of measure and reference ranges for DTM testing, including other relevant demographics on patient's final reports . 2. Interviews with the laboratory director on 09/20/2021 at approximately 2:40 PM in the review room confirmed that the units of measure and the reference range for DTM were not on final reports in 2020 and 2020.