

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 19D0457792	<b>(X3) Date Survey Completed</b> 05/23/2024
<b>Name of Provider or Supplier</b> Laplace Dermatology Clinic	<b>Street Address, City, State</b> 398 Belle Terre Boulevard, Laplace, LA	
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 Recertification survey was performed at LaPlace Dermatology, CLIA ID 19D0457792, on May 23, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5609</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's patient reports, quality control records, and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&amp;E) stains for two (2) of eleven (11) random selection of patients. Findings: 1. Review of random selection of patient reports which included documentation of stain quality on each report, revealed the Laboratory Director, who serves as Testing Personnel, did not document the stain quality for the following two (2) patients: September 19, 2023: LP-328 March 13, 2024: LP-081 2. In interview on May 23, 2024 at 9:45 am, the Lead Medical Assistant stated the stain quality is documented on each patient report. The Lead Medical Assistant confirmed for the identified two (2) patients the stain quality was not documented.</p>
<b>D5793</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic 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 analytic systems</p>

quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment policies, records, and interview with personnel, the laboratory's quality assessment (QA) monitors failed to identify and correct quality issues in the analytic systems. Findings: 1. Review of the laboratory's "Quality Assessment Procedures" revealed the following: "All Quality Control (QC) records such as log sheets that have not been reviewed previously will be reviewed by the Laboratory Director or an appropriate, designated staff member every monthly {sic}. All QA records such as logs of test requisitions, test reports, and receipt and QA of reagents and culture media that have not been reviewed previously will be reviewed by the Laboratory Director or an appropriate, designated staff member every monthly {sic}. The Laboratory Director or an appropriate, designated staff member will conduct meetings with all relevant staff every quarterly {sic}. 2. The laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for two (2) of eleven (11) random selection of patients. Refer to D5609. 3. Review of the laboratory's records revealed the laboratory did not have documentation of monthly QC and QA reviews. 4. In interview on May 23, 2024 at 10:00 am, the Lead Medical Assistant confirmed the Laboratory Director does not perform/document monthly reviews of QC or QA as indicated in their policy.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5609.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.