

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1093316	<b>(X3) Date Survey Completed</b>  03/24/2023
<b>Name of Provider or Supplier</b>  Tulane Dermatology & Multispecialty	<b>Street Address, City, State</b>  101 E Judge Tanner Blvd, Suite 406, Covington, 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 Certification survey was performed on March 24, 2023 at Tulane Dermatology & Multispecialty Clinic, CLIA ID # 19D1093316. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5401</b>	<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 review of the laboratory's policies and interview with personnel, the laboratory failed to have complete policies and procedures. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include retention requirements for the analytic systems records, to include, but not limited to, quality control logs, patient test reports, maintenance and temperature logs. 2. In interview on March 24, 2023 at 2:00 pm, the Histotech confirmed the laboratory's current policies did not include record retention of analytic system documents.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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 review of random selection of patient final test reports and interview with personnel, the laboratory failed to include the address of the laboratory where testing was performed for three (3) of five (5) patients reviewed for March 6, 2023. Findings:  
1. Review of patient final test reports for March 6, 2023 revealed the address of the laboratory that performed the testing was not included for the following: Patient JLC-22-019 Patient JLC-22-020 Patient JLC-22-022  
2. In interview on March 6, 2023 at 1:55 pm, the Histotech confirmed the identified patient final reports did not include the correct address of the laboratory that performed the testing.

**D6098**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.