

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1093316	<b>(X3) Date Survey Completed</b>  05/28/2025
<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 Recertification survey was performed at Tulane Dermatology & Multispecialty Clinic, CLIA ID 19D1093316, on May 28, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 the laboratory's policies, records, test menu, and interview with personnel, the laboratory failed to verify the accuracy of Histopathology testing at least twice annually as required for one (1) of two (2) years reviewed . Findings: 1. Review of the laboratory's "Quality Assurance/Assessment" policy revealed "The laboratory sends randomly selected cases for review by a dermatopathologist on a quarterly basis. Ten percent of all cases will be reviewed and results will be recorded on the attached review sheet." 2. Review of the laboratory's records revealed the laboratory did not have documentation of verification of the accuracy of Histopathology testing at least twice annually for 2024. 3. In interview on May 28, 2025 at 3:44 pm, the Histotech stated the 2024 cases for quarterly review were sent off late and the laboratory was awaiting the reports. The Histotech confirmed the laboratory did not verify the accuracy of Histopathology testing for 2024. 4. Review of the laboratory's test menu revealed the laboratory performs 200 Histopathology cases annually.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p>

(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 review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions when the cryostat temperature was outside of acceptable limits for two (2) of seventeen (17) days reviewed in 2025. Findings: 1. Review of the laboratory's "Cryostat Maintenance" policy revealed "cryostat range is from -15C to -30C. Console temperature is to be recorded daily. Any variance out of range is to be recorded and reported to supervisor. If the range variance cannot be repaired, the console will not be used until serviced." 2. Review of the laboratory's cryostat temperature logs revealed the acceptable temperature range for the cryostat was -15 degrees Celsius (C) to -30 degrees C. 3. Review of the laboratory's 2025 cryostat temperature log, January 1, 2025 through May 28, 2025, revealed the cryostat temperature was outside acceptable limits without documentation of corrective actions for the following dates: February 3, 2025 documented cryostat temperature -31 degrees C March 10, 2025 documented cryostat temperature -31 degrees C 4. In interview on March 28, 2025 at 3:42 pm, the Histotech confirmed no corrective actions for temperatures outside of acceptable limits were performed for the two (2) identified dates.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

(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:

\*\*\* Repeat deficiency from survey performed March 24, 2023 \*\*\* 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 two (2) of eight (8) patients reviewed. Findings: 1. Review of random selection of patient final test reports revealed the address of the laboratory that performed the testing was not included for the following two (2) patients: Patient JLC-24-047 Patient JLC-25-053 2. In interview on May 28, 2025 at 4:18 pm, the Histotech confirmed the identified patient final reports did not include the correct address of the laboratory that performed the testing.

<p><b>D5891</b></p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Refer to D5805.</p>
<p><b>D6087</b></p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5217.</p>
<p><b>D6093</b></p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the quality assessment programs were established to assure the quality of laboratory testing. Refer to D5891.</p>
<p><b>D6096</b></p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)</p> <p>(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.</p>
<p><b>D6098</b></p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p>

(e)(8) 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 patient final reports included required pertinent information. Refer to D5805.