Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0885259	06/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Tulane Medical Center-Dermatology	4720 South I10 Service Rd West, Metairie, LA	

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
D0000	A Recertification survey was performed at Tulane Medical Center-Dermatology, CLIA ID 19D0885259, on June 3, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. 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 June 3, 2025 at 3:42 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 100 Histopathology cases annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. 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 define their acceptable cryostat temperature range. Findings: 1. Review of the laboratory's "Cryostat Maintenance" policy revealed "The Leica CM1520 cryostat range is from -15 C to -30 C." 2. Review of the laboratory's policy under the "Test Procedure" section revealed "cryostat, which is kept within a band between -20 C to -30 C at all times during tissue processing." 3. In interview on June 3, 2025 at 3:45 pm, the Histotech confirmed the cryostat temperature was not defined.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of policies, and interview with personnel, the laboratory failed to label marking dyes stored in secondary containers with lot numbers and expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on June 3, 2025 at 2:57 pm revealed one (1) red marking dye, one (1) blue marking dye, and one (1) green marking dye in the corresponding color bottles with a line drawn through the expiration date and "refill" written on each bottle. 2. Review of the laboratory's policies under the "Preparation and Labeling" section revealed "All reagents are to be labeled with the following information: a) Content and quantity, concentration or titer, b) storage requirements, c) date prepared or reconstituted by laboratory, and d) expiration date." 3. In interview on June 3, 2025 at 3:01 pm, the Histotech stated he refilled the smaller secondary bottles from the master dye bottles located in the cabinet. The Histotech confirmed the secondary bottles were not labeled with the master bottles' lot numbers and expiration dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, maintenance records, and interview with personnel, the laboratory failed to perform microscope maintenance per policy for one (1) of three (3) six month cleaning dates reviewed. Findings: 1. Review of the laboratory's policies revealed "Cleaning and routine user-level maintenance of all equipment (cryostat, linear stainer, fume hood/adsorber {sic}, microscope) will be performed per manufacturer's recommendations and documented appropriately." 2. Review of the laboratory's "Microscope Maintenance" revealed "The microscope is cleaned every 6 months. The microscope is serviced every 5 years." 3. Review of the laboratory's "Maintenance Record-Microscope" log revealed the following microscope tasks to be performed at six (6) months: "stage and ocular cleaning and grounding/cleaning." 4. Further review of the laboratory's "Maintenance Record-Microscope" log revealed the six (6) month cleaning of the stage and oculars and grounding/cleaning was not performed in 2025, due February 2025. 5. In interview on June 3, 2025 at 3:43 pm, the Histotech stated performance of the microscope maintenance got off schedule and the six month maintenance was not performed in 2025.
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: 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 six (6) 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 six (6) patients: Patient JLN-24-061 Patient JLN-24-096 Patient JLN-25-007 Patient JLN-25-033 Patient JLN-25-061 Patient JLN-25-076 2. In interview on June 3, 2025 at 3:42 pm, the Histotech stated the laboratory moved to its current location April 8, 2024. The Histotech confirmed the identified patient final reports did not include the correct address of the laboratory that performed the testing.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the

	Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of Histopathology testing at least twice annually as required for one (1) of two (2) years reviewed. Refer to D5217. 2. The laboratory failed to define their acceptable cryostat temperature range. Refer to D5413. 3. The laboratory failed to label marking dyes stored in secondary containers with lot numbers and expiration dates. Refer to D5415.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were followed to ensure acceptable levels of test performance. Refer to D5433.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (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.