Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0885259	04/14/2023
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 on April 14, 2023 at Tulane Dermatology, CLIA ID # 19D0885259. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed a policy with record retention requirements; however, the policy did not address retention of quality control and temperature logs. 2. In interview on April 14, 2023 at 4 p.m., the Histotech confirmed the manual did not contain the record retention information identified above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual and patient records, as well as interview with laboratory personnel, the laboratory failed to follow the laboratory's procedure for labeling of Mohs patient slides. Findings: 1. Review of the laboratory's policy and procedure manual revealed two policies which include instructions on how to label slides that were different from how the laboratory labeled slides . a) The laboratory's policy and procedure "Mohs Histopathology /Micrographic Surgery" section 3.4.9 revealed "Slides are labeled with Mohs accession number, patient name and date of birth, date, and tissue section number corresponding to the Mohs map." b) The laboratory's policy and procedure "How to Prepare Tissue for Sections" revealed to label slides with accession number (doctor, location, year, case number) and block number. c) Slides reviewed were labeled with accession number, date, stage, and block number. 2. In interview on April 14, 2023 at 2:45 p.m., the Histotech confirmed the instructions for labeling in the policies did not match the current way slides are labeled.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation and review of the laboratory's policies and temperature logs, the laboratory failed to define the acceptable temperature limits for operation of the cryostat. Findings: 1. Observation by surveyors on April 14, 2023 at 1:07 p.m. during the laboratory tour revealed the laboratory used a Leica cryostat. 2. Review of the laboratory's policy and procedure manual revealed two policies with differing acceptable temperature ranges for the cryostat. a) The laboratory's policy and procedure "Mohs Histopathology/Micrographic Surgery" section "Test Procedure" stated "...-20C to -35C at all times during tissue processing." b) The laboratory's policy and procedure "Lab Maintenance" section "Cryostat Maintenance" stated "The

	Leica CM1520 cryostat range is from -15C to -30C. Any variance out of the range is to be recorded and reported to the supervisor." 3) The laboratory's temperature log for the cryostat stated an acceptable temperature range of -15C to -30C.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual, and interview with laboratory personnel, the laboratory failed to ensure that all laboratory reagents are not used beyond their expiration date. Findings: 1. During the lab tour on April 14, 2023 at 1:07 p.m., surveyors observed the following expired items: a) Leica tissue freezing medium, lot 03820610, expiration date December 2022, one bottle b) Surgipath tissue marking and margin dyes, ref 3801754 Yellow, lot 011422, expiration date January 14, 2023, one bottle c) Surgipath tissue marking and margin dyes, ref 3801755 Red, lot 033022, expiration date March 30, 2023, one bottle d) Surgipath tissue marking and margin dyes, ref 3801753 Black, expiration date November 1, 2022, one bottle e) Surgipath tissue marking and margin dyes, ref 3801752 Green, lot 032922, expiration date March 29, 2023 one bottle f) Acetone, lot 067239, expiration date June 2020, one bottle 2. Review of the laboratory's policy "Mohs Histopathology/Micrographic Surgery" section "4.3 Storage, Use and Handling" revealed "Do not use a reagent after expiration date. All reagent expiration dates are checked monthly to ensure removal from use before expiration. Each review of reagent expiration dates is documented on the expiration date log." 3. In interview on April 14, 2023 at 1:15 p.m., the Histotech confirmed the freezing medium was expired. He stated he uses a different freezing medium than the one that was expired. In interview on April 14, 2023 at 1:32 p.m., he confirmed the other items listed were expired and stated these were in a place he stores items to be discarded.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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 temperature logs and interview with personnel, the laboratory failed to document corrective actions performed when the cryostat temperature was not maintained between 15 degrees and 30 degrees Celsius. Findings: 1. Review of the laboratory's temperature logs for the cryostat revealed the acceptable range to be

	15 degrees to 30 degrees Celsius. 2. Further review of the temperature logs revealed the temperature of the cryostat was documented as -31 degrees Celsius without corrective action for the following eight (8) of forty-two (42) days: June 1, 2022 November 2, 2022 November 9, 2022 November 16, 2022 November 30, 2022 December 7, 2022 December 14, 2022 December 21, 2022 3. In interview on April 14, 2023 at 2:59 p.m., the Histotech said he added liquid nitrogen on the listed days to make the cryostat colder because he was cutting fatty tissues. He confirmed there was no documentation of corrective actions.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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. This STANDARD is not met as evidenced by: Based on review of patient test records and the laboratory's procedure manual and interview with personnel, the laboratory failed to establish a Quality Assessment Plan that would monitor, identify, and correct quality issues in the Post Analytic system. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had a quality assurance/assessment section; however, it failed to identify missing documentation for one (1) of eight (8) patients reviewed. 2. Review of the laboratory's procedure "Mohs Histopathology/Micrographic Surgery" section "Quality Assurance/Assessment" revealed "The Laboratory Director (Mohs surgeon) will monitor all aspects of the laboratory and make certain that all testing complies with the Individual testing policy and procedure protocols." 3. Review of patient test records revealed case JLN-21-117 did not have complete documentation of clear margins for the Mohs map. 4. In interview on April 14, 2023 at 2:28 p.m., the Laboratory Director confirmed the report did not have documentation that no tumor was present.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. 1. The laboratory failed to define the acceptable temperature limits for operation of the cryostat. Refer to D5413. 2. The laboratory failed to ensure that all laboratory reagents are not used beyond their expiration date. Refer to D5417.
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 D5891.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. 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 laboratory's policies occurred. Refer to D5781.
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 personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. 1. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401. 2. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403.