Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1093316	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Tulane Dermatology & Multispecialty	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An Initial survey was performed on May 19, 2021 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.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. 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 a system in place for reporting complaints. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a written procedure for reporting complaints, including who is responsible for handling. 2. In interview on May 19, 2021 at 10:30 am, the clinic manager confirmed the laboratory did not have a written procedure for reporting/handling complaints.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to

	establish a written policy for competency assessments for testing personnel who perform Histopathology testing. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director performs Histopathology testing. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy for competency assessments of testing personnel that included frequency of performance and the minimal requirement of the following six (6) procedures: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. Review of personnel records revealed the Laboratory Director did not have competency assessments performed. 4. In interview on May 19, 2021 at 10:30 am, the clinic manager confirmed the laboratory's policy and procedure manual did not include a written policy for competency assessment for testing personnel.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's "Moh's Lab Policies & Procedures" revealed the Laboratory Director did not approve/sign the manual. 2. In interview on May 19, 2021 at 10:09 am, the Moh's tech stated the Laboratory Director did not sign the manual; the Laboratory Director's name was typed.
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 direct observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory reagents did not exceed their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on May 19, 2021 at 9:18 am revealed the following expired item: a) Xylene Substitute, Lot 054802, Expiration Date: 06/19, Quantity: one (1) bottle 2. In interview on May 19, 2021 at 9:26 am, the Moh's tech confirmed the identified reagent was expired.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's cryostat maintenance logs and interview with personnel, the laboratory failed to perform monthly maintenance for the cryostat per laboratory policy for three (3) of eleven (11) months reviewed. Findings: 1. Review of the laboratory's 2020 "Maintenance Record-Cryostat" logs revealed the following tasks: a) "Clean interior day of surgery" b) "Thermometer check monthly" c) "Moving components monthly" d) "Clean air filter monthly" e) "Preventative maintenance" (frequency was not defined) f) "Defrost-end of month" g) "Any problems-notify supervisor" 2. Review of the laboratory's 2021 "Maintenance Record-Cryostat" logs revealed the following tasks: a) "Clean interior" b) "Thermometer Check Monthly" c) "Moving Components Monthly" d) "Clean Air Filter Monthly" e) "Preventative Maintenance" (frequency was not defined) f) "Defrost of Machine PRN" g) "Problems /Supervisor Attention" 3. Review of laboratory's "Maintenance Record-Cryostat" logs for July 2020 through May 2021 revealed the following monthly maintenance tasks were not performed: a) December 2020: Monthly: Thermometer Check, Moving Components, Defrost, and Clean Air Filter b) January 2021: Monthly: Thermometer Check, Moving Components, and Clean Air Filter c) April 2021: Monthly: Clean Air Filter 4. In interview on May 19, 2021 at 9:39 am, the Moh's tech confirmed the laboratory did not perform the cryostat maintenance per laboratory policy. II. Based on review of the laboratory's slide stainer maintenance logs and interview with personnel, the laboratory failed to perform maintenance for the slide stainer per laboratory policy for seven (7) of eleven (11) months reviewed. Findings: 1. Review of the laboratory's "Maintenance Log for Linistain Stainer" revealed the following tasks: "Maintenance required on a periodic basis includes the following: Frequency: Bi-weekly:" a) "Cleaning of the case" b) "Internal cleaning" c) "Cleaning and Disinfecting the Staining Jars and Evaporation Covers" 2. Review of the laboratory's "Maintenance Log for Linistain Stainer" for July 2020 through May 2021 revealed the identified bi-weekly maintenance tasks were not performed for the following dates: September 2020: due September 14, 2020 November 2020: due November 16, 2020 December 2020: due December 14, 2020 and December 28, 2020 January 2021: due week of January 18, 2021 February 2021: due week of February 15, 2021 March 2021: due week of March 1, 2021 April 2021: due week of April 26, 2021 3. In interview on May 19, 2021 at 9:57 am, the Moh's tech stated there were gaps in performance of the biweekly maintenance. The Moh's tech confirmed maintenance for the slide stainer were not performed for the identified dates.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Refer to D5407. 2. The laboratory failed to ensure laboratory reagents did not exceed their expiration dates. Refer to D5417. 3. The laboratory failed to perform monthly maintenance for the cryostat per laboratory policy for three (3) of eleven (11) months reviewed. Refer to D5433 I. 4. The laboratory failed to perform maintenance for the slide stainer per laboratory policy for seven (7) of eleven (11) months reviewed. Refer to D5433 II.
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 by surveyor and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. 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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 review of maintenance logs and interview with personnel, the Laboratory Director failed to ensure required maintenance was performed to ensure acceptable levels of performance. Findings: 1. The laboratory failed to perform monthly maintenance for the cryostat per laboratory policy for three (3) of eleven (11) months

	reviewed. Refer to D5433 I. 2. The laboratory failed to perform maintenance for the slide stainer per laboratory policy for seven (7) of eleven (11) months reviewed. Refer to D5433 II.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D5209.
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 review of the laboratory's policies and procedures, 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. Findings: 1. The laboratory failed to have a system in place for reporting complaints. Refer to D5205. 2. The laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Refer to D5407.