Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2120244	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Trieu Dermatology, Llc	1525 Lapalco Blvd, Suite 20, Harvey, 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 Trieu Dermatology, LLC, CLIA ID 19D2120244, on January 16, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of patient logs, patient slides, patient case reports, and interview with personnel, the laboratory failed to establish written procedures to ensure positive identification of patient specimens from receipt through reporting of results for two (2) of nine (9) patients reviewed. Findings: 1. Review of the laboratory's "Monthly Quality Assurance Overview Policy" revealed "On a monthly basis all the slides, logs, and forms will be evaluated by the laboratory director and updated in the Monthly Quality Assurance Overview to ensure that all procedures and protocols are up to date and correct." 2. Review of random selection of patient logs, patient case reports with accompanying slides revealed the written case numbers on the slides and Mohs log book did not match the written case numbers on the patient case reports for the following two (2) of nine (9) patients reviewed: Patient 1: Mohs log book and slide- Case # DT24-730; Patient case report- Case # DT24-731 Patient 2: Mohs log book and slide- Case # DT24-731; Patient case report- Case # DT24-730 3. Review of the laboratory's "Monthly Quality Assurance Overview" logs for 2024 and the laboratory's records revealed the laboratory did not have documentation of corrective actions for the two (2) identified patients. 4. In interview on January 16, 2025 at 11:05

	am, the Medical Assistant confirmed the case number on the identified patients' slides did not match the patient case reports.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 policies and interview with personnel, the laboratory failed to have a complete policy for twice a year verification for Histopathology testing. Findings: 1. Review of the laboratory's "Proficiency Testing /Quality Assessment Program" policy revealed "Proficiency by a consulting dermatopathologist or another Mohs surgeon will be done four times a year. This form is for evaluation of diagnostic abilities of the Mohs surgeon and the quality of the slides produced by the histotechnologist." 2. Further review of the "Proficiency Testing/Quality Assessment Program" policy revealed the laboratory did not include corrective actions for result discrepancies. 3. In interview on January 16, 2025 at 10: 43 am, the Medical Assistant confirmed the written policy did not include actions to take if there is a discrepancy in the results.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, CMS 209 form, patient test logs, quality control records, and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Toluidine Blue stain for fifty one (51) of fifty seven (57) randomly selected test dates in 2023. Findings: 1. Review of the laboratory's "Control Slides" policy revealed "The first frozen section of the day (tumor tissue from the first lesion) serves as the stain control slide. It is checked by the surgeon/pathologist when he/she becomes available." 2. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the Laboratory Director also serves as the Testing Personnel. 3. Review of random selection of patient test logs and quality control records revealed the Laboratory Director did not document the stain quality for testing performed on the following dates, with a total of 461 patients reported: May 23, 2023 May 24, 2023 May 31, 2023 June 7, 2023 June 13, 2023 June 14, 2023 June 21, 2023 June 27, 2023 June 28, 2023 July 5, 2023 July 6, 2023 July 7, 2023 July 10, 2023 July 12, 2023 July 18, 2023 July 19, 2023 July 25, 2023 July 26, 2023 July 31, 2023 August 2, 2023 August 4, 2023 August 8, 2023 August 9, 2023 August 15, 2023 August 16, 2023 August 23, 2023 August 29, 2023 August 30, 203 September 5, 2023 September 6, 2023 September 13, 2023 September 19, 2023 September 20, 2023 September 26, 2023 September 27, 2023 October 4, 2023 October 20, 2023 October 11, 2023 October 17, 2023 October 18, 2023 October 19,

	2023 October 25, 2023 October 30, 2023 October 31, 2023 November 1, 2023 November 7, 2023 November 15, 2023 November 21, 2023 November 22, 2023 November 28, 2023 November 29, 2023 4. In interview on January 16, 2025 at 10:43 am, the Medical Assistant confirmed there was no documentation of the Laboratory Director's assessment of the stain quality for the identified dates.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (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; 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 control program was maintained to assure the quality of laboratory testing. Refer to D5609.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and 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. Findings: 1. The laboratory failed to establish written procedures to ensure positive identification of patient specimen from receipt through reporting of results for two (2) of nine (9) patients reviewed. Refer to D5203. 2. The laboratory failed to have a complete policy for twice a year verification for Histopathology testing. Refer to D5401.