Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2120244	03/23/2023
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 on March 23, 2023 at Trieu Dermatology, LLC, CLIA ID # 19D2120244. 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 personnel, the laboratory failed to establish a complete policy and procedure for record retention. Findings: 1. Review of the laboratory's procedure manual revealed a retention policy; however, the laboratory did not address retention of patient reports and quality control records. 2. In interview on March 23, 2023 at 10:10 AM, the Histotech confirmed the policy and procedure manual did not include record retention requirements for patient reports and quality control.
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 review of the laboratory's policies and maintenance logs and interview with personnel, the laboratory failed to define and document the acceptable temperature for operation of the cryostat and document temperature readings for the cryostat. Findings: 1. Review of the laboratory's policy "Frozen Section Workroom Set-up" revealed the following instructions: Cryostat 1. Check temperature and note it in cryostat log book, if out of range. 2. Confirm that the mechanics are working properly. 2. Review of the laboratory's "Cryostat Maintenance Record" for 2023 revealed the laboratory documented "Thermometer Check" performance with a check mark; however, the cryostat thermometer reading is not documented. 3. In interview on March 23, 2023 at 10:43 AM, the Histotech stated the temperature for the cryostat is checked but not documented, and it is always at -20.
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 by surveyors, review of the laboratory's policies, and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyors during the laboratory tour on March 23, 2023 at 09:48 AM revealed the following expired item: -0.5 Toluidine Blue O Alcoholic Solution, Lot 122154, Expiration Date: 5-31-22, Quantity: one (1) bottle 2. Review of the laboratory's policy "Frozen Section Workroom Set-up" section "Supplies" revealed "Make sure adequate supplies (slides, slide marking pens, permanent marking pens, tissue marking dyes, brushes, and solutions) are available and in place. Supplies will be checked on a monthly basis to ensure expired supplies are disposed of properly." 3. In interview on March 23, 2023 at 09:54 AM, the Histotech stated it was the only bottle they had and confirmed the identified bottle was expired.
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. Findings: 1. The laboratory failed to define and document the acceptable temperature for operation of the cryostat and document temperature readings for the cryostat. Refer to D5413. 2. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417.

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 laboratory 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. Refer to D5401.