Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D2120244	**(X3) Date Survey Completed** 02/07/2019
Name of Provider or Supplier Trieu Dermatology, Llc	**Street Address, City, State** 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 Certification Survey was performed on February 7, 2019 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.
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, record review, and interview with personnel, the laboratory failed to ensure marking dyes have not exceeded their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on February 7, 2019 revealed the following expired items: a) Mark IT Tissue Marking Dye, Green, Lot # 393019, Expiration Date: 11/2018, Quantity: one (1) bottle b) Mark IT Tissue Marking Dye, Orange, Lot # 393015, Expiration Date: 11/2018, Quantity: one (1) bottle c) Mark IT Tissue Marking Dye, Red, Lot # 389377, Expiration Date: 10/2018, Quantity: one (1) bottle d) Mark IT Tissue Marking Dye, Black, Lot # 394875, Expiration Date: 11 /2018, Quantity: one (1) bottle e) Mark IT Tissue Marking Dye, Blue, Lot # 389376, Expiration Date: 10/2018, Quantity: one (1) bottle 2. Review of the laboratory's "Expiration of Supplies/Chemicals" policy revealed the following: "Histotech will review supply stock periodically and dispose of expired items in accordance with established procedures." 3. In interview on February 7, 2019 at 1:15 pm, Personnel 1 stated the laboratory maintains a reagent log with expiration dates. 4. Review of the laboratory's "Reagent Receipt Log" revealed the laboratory did not include the identified items on the log. 5. In further interview on February 7, 2019, Personnel 1 stated she was unaware the identified marking dyes had an expiration date.

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 record review and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Histopathology testing. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Personnel 1 serves as the testing personnel 2. Review of random selection of patients and quality control records revealed the laboratory did not have documented QC assessment performed by the testing personnel identified on the laboratory's CMS 209 form (Laboratory Personnel Report) for the following dates: August 31, 2017 December 12, 2017 February 7, 2018 June 11, 2018 September 5, 2018 October 10, 2018 November 27, 2018 January 15, 2019 February 6, 2019 3. In interview on February 7, 2019 at 2:00 pm, Personnel 1 stated the histotech makes a quality control slide, which she examines for stain quality. Personnel 1 stated she is not always the person documenting the acceptability, sometimes it is the histotech who performed the staining.
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 record review and interview with personnel, the laboratory failed to document corrective actions performed when the room humidity was not maintained at less than 60%. Findings: 1. Review of the laboratory's "Daily Temperatures and Humidity For Microscope, Cryostat, Stainer Instrument Log" revealed acceptable room humidity is less than 60%. 2. Further review of the humidity logs for 2017, 2018, and January 2, 2019 through February 6, 2019 revealed the room humidity was outside of acceptable limits without corrective action documentation for the following six (6) dates: January 3, 2018: Recorded humidity 67% January 10, 2018: Recorded humidity 67% February 7, 2018: Recorded humidity 67% February 28, 2018: Recorded humidity 67% April 18, 2018: Recorded humidity 67% January 2, 2019: Recorded humidity 64% 3 In interview on February 7, 2019, Personnel 1 stated if the humidity is above 60%, the air conditioner is adjusted. Personnel 1 further stated the identified dates did not have documented corrective action.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure marking dyes have not exceeded their expiration dates. Refer to D5417. 2. The laboratory failed to ensure testing personnel documented the stain quality for Histopathology testing. Refer to D5609.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications 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.