Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2171402	09/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Legacy Dermatology, Pllc	3140 Legacy Dr Suite 620, Frisco, TX	

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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 and in interview with staff, the laboratory failed to ensure in-use tissue marking dyes had not exceeded their expiration date. Findings Included: 1. During a tour of the laboratory on 09/28/2021 at 11:45 AM, the following expired reagents were observed opened and stored near the grossing station: a. StatLab Red Tissue Marking Dye Lot#9203 Expiration Date: 07/31/2021 b. StatLab Blue Tissue Marking Dye Lot#9212 Expiration Date: 07/31/2021 c. StatLab Black Tissue Marking Dye Lot#9228 Expiration Date: 08/31/2021 d. StatLab Black Tissue Marking Dye

	Lot#9231 Expiration Date: 08/31/2021 2. During the tour of the laboratory on 09/28 /2021 at 11:45 AM, the laboratory representative confirmed the tissue marking dyes listed above were expired.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for H & E staining on each day of patient testing for 3 of 3 months in 2019 (September 2019 - December 2019), 12 of 12 months in 2020 and 8 of 8 months in 2021 (January 2021- August 2021). Findings Included: 1. Review of laboratory quality control records titled, "Quality Control Slide Review by Physician" (Reviewed by laboratory director on 06/05/2021) revealed the following quality control criteria: "Quality Control Results: 1. Air Bubbles 2. Fixation 3. Fixative 4. Nuclear Stain 5. Cytoplasmic Stain 6. Overall Stain Quality For any unacceptable responses what is the corrective action to be taken?" Under each category were boxes to document daily stain quality with "checkmarks" to indicate if the categories were "Good", "Poor" and "Unacceptable". The QC slide review failed to define "Good", "Poor" and "Unacceptable" for H&E intended reactivity. The laboratory failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics. 2. A random review of patient records from 2019, 2020, and 2021 revealed the following dates/patients were reported in which "Air Bubbles, Fixative, Fixation, Nuclear Stain, Cytoplasmic Stain, and Overall Stain Quality" were documented with "Good": a.09/21/2019 Patient Identification (ID)- LD19-1; LD19-2 b. 02/29/2020 Patient Identification (ID)- LD20-15; LD20-16 c. 06/03/2021 Patient Identification (ID)- LD21-40 d. 06/05/2021 Patient Identification (ID)- LD21-59 3. During an interview on 09/28/2021 at 11:35 AM in the facility office, the laboratory representative, after presentation of findings, confirmed the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the H&E stain.