Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0689775	**(X3) Date Survey Completed** 04/28/2023
Name of Provider or Supplier Clear Lake Dermatology	**Street Address, City, State** 13938 Hwy 3 Unit 100, Webster, 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	The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, 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 CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory and staff interview, the laboratory failed to label 15 of 15 secondary containers for reagents used in Hematoxylin and Eosin (H&E) Staining Protocol. Findings included: 1. Surveyor's observations on 04 /28/2023 at 0940 hours in the laboratory revealed 15 containers with various solutions used in H&E staining of histopathology slides. None of the 15 containers were labeled with the identity of the contained solution/reagent, the reagent's lot number or

	expiration date. A legend with the H&E Staining Protocol was posted adjascent to the staining containers, but the containers did not have labels corresponding to the legend. The laboratory did not record at any time the reagents in use lot numbers or expiration dates. Cross refer to D5609. 2. In an interview on 04/28/2023 at 0940 hours in the laboratory, the laboratory's Histotechnologist on duty, after review of the unlabeled secondary containers, confirmed the findings.
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 surveyor's observations in the laboratory, review of laboratory's patient test logs and submitted annual test volumes, and staff interview, the laboratory failed to ensure 6 of 14 laboratory products were not used in testing when they have exceeded their expiration date. Findings included: 1. Surveyor's observations on 04/28/2023 at 0935 hours in the laboratory revealed the following 6 of 14 laboratory products used for laboratory procedures had exceeded their expiration date: Stat Lab Medical Produces Blue Tissue Marking Dye Lot: 069226 Expired: 2020-08-01 Stat Lab Medical Produces Green Tissue Marking Dye Lot: 069210 Expired: 2020-09-01 Stat Lab Medical Produces Red Tissue Marking Dye Lot: 069136 Expired: 2020-09-01 Gerinex Topical Light Mineral Oil USP Lot: 1508036 Expired: 07-2019 Delasko KOHD 20% Potassium Hydroxide (KOH) with DMSO Lot: K187PI Expired: 2021-07-31 BBC Biochemical Optic Mount X Lot: 107970 Expired: 2022-10-31 2. Review of laboratory's patient test logs and submitted annual test volumes for 2021, 2022 and 2023 revealed: a. Laboratory performed approximately 342 histopathology test procedures annually where expired Tissue Marking Dyes were used since August of 2020. b. Laboratory performed approximately 2 mineral oil test procedures annually where expired Topical Light Mineral Oil USP was used since July of 2019. c. Laboratory performed approximately 72 KOH test procedures where expired Delasko KOHD 20% Potassium Hydroxide with DMSO was used since July of 2021. 3. In an interview on 04/28/2023 at 0940 hours in the laboratory, the laboratory's Histotechnologist on duty, after review of the expired products, confirmed the findings.
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 H&E (hematoxylin and eosin) stain quality control (QC) records for 2021 and 2022, laboratory's policies/procedures and staff interview, the laboratory failed to document lot numbers and expiration dates of stain reagents in use for H&E stain, one of three procedures performed in the laboratory. Findings included: 1. Review of the laboratory's H&E stain QC records for 2021 and

	2022 revealed there was no documentation of reagent's lot numbers or expiration dates for any of the stain reagents in use at any time during that interval. 2. Review of laboratory's policies/procedures revealed there was no protocol in place addressing documentation of reagent lot numbers and expiration dates and/or dates of placement in use. 3. In an interview on 04/28/2023 at 0940 hours in the laboratory, the laboratory's Histotechnologist on duty confirmed the findings.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the laboratory's quality control records, patient test logs/annual test volumes, policies and procedures and staff interview, the Laboratory Director failed to ensure the laboratory provided quality laboratory services for all aspects of test performance. Refer to D5415, D5417 and D5609.
D6179	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(5) Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director. This STANDARD is not met as evidenced by: Based on surveyor's observations, patient test logs/annual test volumes, policies and procedures and staff interview it was determined 5 of 5 testing personnel failed to identify and correct issues with expired reagents. Refer to D5417.