Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0689775	(X3) Date Survey Completed 12/08/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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.
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 a review of laboratory's policies, the laboratory's Weekly H&E Quality Control logs from January 2020 to December 2021, a review of patient test records, and staff interview, it was revealed that the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for five of 75 days reviewed from January 2020 to December 2021. Findings: 1. A review of the laboratory's policies revealed the laboratory documented the intended reactivity of the H&E stain on the 'Weekly H&E Quality Control' logs

	every day of patient testing (this laboratory only performed Mohs once a week), using tissue sample from the first patient case of the day. 2. Review of the laboratory's Weekly H&E Quality Control logs from January 2020 to December 2021 revealed no documentation of the intended reactivity for the H&E stain on the following 5 days: 2 /7/20 5/22/20 9/18/20 1/29/21 2/26/21 3. A review of patient test records revealed the following patients were tested on days when the intended reactivity of the H&E slide was not documented: Date: 2/7/20 Patient: MS20-030, MS20--031, MS20-032, MS20-033, MS20-034, MS20-035, MS20-036, MS20-037, MS20-038 Date: 5/22/20 Patient: MS20-102, MS20-103, MS20-104, MS20-105, MS20-106, MS20-107, MS20-108, MS20-109, MS20-110 Date: 9/18/20 Patient: MS20-203, MS20-204, MS20-205, MS20-206, MS20-207 Date: 1/29/21 Patient: MS21-016, MS21-017, MS21-018, MS21-019, MS21-020, MS21-021, MS21-022 Date: 2/26/21 Patient: MS21-30, MS21-31, MS21-32, MS21-33, MS21-34, MS21-35, MS21-36, MS21-37, MS21-38 4. An interview with the owner on 12/8/21 at 9:45 a.m. in his office, after review of the records, confirmed the above findings.
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 a review of the laboratory's Humidity and Temperature logs for 2020 and 2021, and staff interview, it was revealed that the laboratory failed to have documentation of performing corrective actions when the laboratory's room temperature was documented outside the acceptable range for 40 of 75 days from January 2020 to December 2021. Findings include: 1. A review of the laboratory's Humidity and Temperature logs from January 3, 2020 to December 3, 2021 revealed the laboratory had a defined acceptable range of 72 - 76 degrees for the room temperature. 2. Further review of the Humidity and Temperature logs revealed the following 40 days where the documented room temperature was outside the laboratory's acceptable range: 3/6/20 77.6 3/13/20 80.3 3/20/20 77.8 5/8/20 77.8 5/15 /20 77.2 5/22/20 78.1 5/29/20 77.8 6/5/20 77.2 6/19/20 78.3 7/3/20 77.9 7/10/20 78.7 7 /17/20 77.2 7/24/20 78.7 7/31/20 78.8 8/7/20 77.8 8/14/20 78.8 8/21/20 77.2 9/4/20 77.4 9/11/20 78.5 9/17/20 77.8 9/25/20 78.3 10/9/20 77.4 10/16/20 78.1 10/23/20 77.4 11/6/20 76.3 11/13/20 77.4 11/20/20 76.7 12/4/20 76.5 12/11/20 76.5 12/28/20 77.2 1 /22/21 76.3 7/9/21 77.8 7/16/21 77.6 7/30/21 79 8/6/21 77.2 8/13/21 77.8 8/20/21 77.4 9/24/21 77.8 10/1/21 78.3 12/3/21 76.9 3. The owner was asked to provide documentation of performing corrective actions when the room temperature was outside of the acceptable range. No documentation was provided. 4. An interview with the owner on 12/8/21 at 9:30 a.m. in his office, after review of the records, confirmed the above findings.