Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1106549	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Complete Dermatology	7616 Branford Pl, Ste 240, Sugar Land, 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to have documentation of performing accuracy assessments twice annually in 2020 for the grossing of histology specimens. Findings include: 1. The laboratory supervisor was asked to provide documentation of performing accuracy assessments twice annually in 2020 for the grossing of histology specimens. No documentation was provided. 2. An interview with the laboratory supervisor on 3/9/21 at 2:07 p.m. in the office revealed the laboratory did not perform twice annual accuracy assessments for the grossing of histology specimens in 2020. This confirmed the above findings.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory's procedure manual, a review of the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to have a written procedure for how it will ensure the accuracy, at least twice annually, for the grossing of histology specimens Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory failed to have a written procedure for how it will perform the twice annual accuracy assessments for the grossing of histology specimens. 2. An interview with the laboratory supervisor on 3/9/21 at 14:07 p.m. in the office, confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, a review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure documentation of site-specific training for 1 of 2 testing personnel performing high complexity testing- Mohs. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 3/5/21) revealed the the laboratory identified 2 testing personnel performing high complexity testing- Mohs. 2. A review of the laboratory's personnel records revealed testing person #4 had no documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- Mohs. 3. An interview with the office manager on

	3/9/21 at 3:00 p.m. in the office, after review of the records, stated that testing person #4 was performing Mohs surgery while testing person #2 was on maternity leave. No on-site training was documented. This confirmed the above findings.