

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2141565	<b>(X3) Date Survey Completed</b> 04/09/2025
<b>Name of Provider or Supplier</b> Complete Dermatology	<b>Street Address, City, State</b> 508 Medical Center Blvd #380, Conroe, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced survey of the laboratory was conducted on 04/09/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, test accuracy verification records and staff interview, the laboratory failed to document twice annual test accuracy verification for one of four accuracy verification events in 2023 and 2024. Findings included: 1. Review of laboratory's policy "V. Other: ... B. Proficiency Testing" revealed: "Purpose: Proficiency by a consulting dermatopathologist or another MOHS Surgeon will be done two times a year." 2. Review of laboratory's twice annual test accuracy verification records for 2023 and 2024 revealed the laboratory documented only one test accuracy verification event for 2024 tests. Test accuracy verifications were documented as follows: Event: Documented: 1st event 2023 06/21/2023 2nd event 2023 10/10/2023 Event 2024 01/13/2025 3. In an interview on 04/09/2025 at 1040 hours in the office, the facility's Practice Manager (as indicated on submitted Entrance/Exit Conference document) confirmed the findings.</p>
<b>D6107</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(15)</p> <p>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic,</p>

analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory's personnel records, policies/procedures and staff interview, the Laboratory Director failed to specify in writing the responsibilities and duties of four of four personnel employed by the laboratory in 2023 and 2024.

Findings included: 1. Review of laboratory's personnel records revealed the laboratory had two employees with multiple positions involved in the testing component of tissue examination, a laboratory director (LD)/clinical consultant and a clinical consultant (CC)/technical supervisor (TS)/general supervisor (GS)/testing person (TP). The laboratory also employed two histotechs for preparation of histology slides, not involved in testing. 2. Further review of the laboratory's personnel records revealed there was no documentation of delegation of specific duties to the individuals employed by the facility. 3. Review of laboratory's policies/procedures in the "Complete Dermatology - Conroe; Laboratory Manual" revealed the policies /procedures did not define the duties and responsibilities of each person employed by the laboratory, nor competency assessment requirements for the consultant (CC) /supervisory (TS/GS)/histotech positions. 4. In an interview on 04/09/2025 at 1040 hours in the office, the facility's Practice Manager (as indicated on submitted Entrance /Exit Conference document) confirmed the findings.