

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2156583	<b>(X3) Date Survey Completed</b>  11/07/2023
<b>Name of Provider or Supplier</b>  Concierge Dermatology	<b>Street Address, City, State</b>  1910 W Henderson St Suite 100, Cleburne, 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>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory records, direct observation, and staff interview the laboratory failed to ensure patent histopathology (Mohs) slides were labeled with at least two unique patient identifiers for 34 of 34 patient Mohs slides in 2023 (random review October to November). Findings included: 1. Review of the laboratory's policy titled "Embedding and Cutting Frozen Sections" revealed: Procedure: "2. The reverse slide mount method is used for embedding. Each slide will be labeled with the patient name, stage and piece number, slide number and Mohs accession number Mohs Accession Number is assigned by location and year (ex: DM17-001) Stages are Roman numeral: Examples: 1, II, III, IV, V, etc. Piece number is the number of piece(s) the surgeon divides the tissue into. Slide number is an alphanumeric number: Examples: A- first slide, B- second slide, C- third slide, etc." An example of how to label a slide was illustrated in the policy: "Doe, J. I-1A CM17-001" The laboratory policy did not include labeling instructions to reliably identify patients using at least two unique patient identifiers to distinguish between specimens. 2. Review of the laboratory records titled "Accession Log" revealed: a. Mohs Case Number b. Patients Name (written as "Last Name, First Name") 3. A random review of patient slides from 2023 (October to November) revealed the following 34 slides labeled with a patient last name, stage and piece number, and a Mohs accession</p>

number.: 10/11/2023 Mohs Case #'s 151, 152, 153 10/18/2023 Mohs Case #'s: 154, 155 10/25/2023 Mohs Case #'s: 156, 157 11/1/2023 Mohs Case #'s 158, 159, 160 The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least two unique patient identifiers. 4. During the exit interview on 11/07/2023 at 12:00 p.m., the Histotechnician after review of records, confirmed the above findings.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of patient records of histopathology Mohs maps and confirmed in staff interview, the laboratory failed to include the testing facility address for 10 of 10 patients in 2023 (random review October to November). Findings included: 1. Review of patient records from 2023 (random sampling) revealed the following 10 histopathology Mohs maps which did not include the testing facility address: 10/11/2023 Mohs Case #'s: 151, 152, 153 10/18/2023 Mohs Case #'s 154, 155 10/25/2023 Mohs Case #'s 156, 157 11/1/2023 Mohs Case #'s 158, 159, 160 2. During the exit interview on 11/07/2023 at 12:00 p.m., the Histotechnician was asked if the histopathology maps reviewed were uploaded directly to the patient's medical record, and he stated "yes." This confirmed the above findings.