

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2171402	(X3) Date Survey Completed 04/25/2023
Name of Provider or Supplier Legacy Dermatology, PLLC	Street Address, City, State 3140 Legacy Dr Suite 620, Frisco, 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	An announced recertification survey conducted 04/25/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers for 44 of 44 slides from 2022 (March, April, and June) and 2023 (January and February). The findings include: 1. Review of the laboratory policy titled "DAILY LAB MAINTENANCE" revealed: "Slides: Slides are placed in numerical order on the slide folders. Slides are labeled with accession number, stage number, and level/deeper/recut." The laboratory policy did not include labeling instructions to reliably identify patients using at least 2 unique patient identifiers to distinguish between specimens. 2. A random review of patient slides from 2022 (March, April, and June) and 2023 (January and February) revealed 44 slides labeled with a patient last name and first initial, Mohs accession number, stage number with level, and date of service. The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers. 3. During an interview on 04/25/2023 at 12:30 p.m., the Chief Operations Officer confirmed the above findings.</p>

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 test reports and confirmed in interview, the laboratory failed to include the address of the testing facility on 15 of 15 Mohs maps (random review) in 2022 (March, April, and June) and 2023 (January and February). The findings include: 1. A random review of patient test reports from 2022 (March, April, and June) and 2023 (January and February) revealed the following 15 Mohs maps missing the address of the testing facility: 03/30/2022 Mohs Accession #'s: LD22-047, LD22-048, LD22-049 04/13/2022 Mohs Accession #'s: LD22-060, LD22-062, LD22-063 06/09/2022 Mohs Accession #'s: LD22-130, LD22-131, LD22-132 01/26/2023 Mohs Accession #'s: LD23-016, LD23-017, LD23-018 02/09/2023 Mohs Accession #'s: LD23-021, LD23-022, LD23-024, 2. During an interview on 04/25/2023 at 12:30 p.m., the Chief Operations Officer confirmed the above findings.