

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2097163	(X3) Date Survey Completed 04/05/2019
Name of Provider or Supplier Legacy Dermatology Pllc	Street Address, City, State 320 W 500 S Suite 210, Bountiful, UT	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY 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 Mohs test log review, Mohs maps review, frozen section slide review, surgical pathology test reports review, and confirmation by staff, the laboratory reports failed to include the case number of the specimen for 11 of 11 test reports reviewed for Mohs micrographic frozen section specimens reviewed from 04/05/2017 to 03/14/2019. Findings include: 1. Mohs test log and maps identified patients by the date of surgery, case number and patient name and location. 2. Mohs surgical chart report did not include the case number to correlate the slides with the surgical reports. 3. Case slides review included the patient's name, case number, and date. 4. In an interview with the laboratory staff on 04/05/2019 at approximately 11:15 A.M. the laboratory staff confirmed the surgical report did not include the case number as did the log, map and slides.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
Based on stain quality control records review, lack of documentation and confirmation by staff, the laboratory failed to record Hematoxylin and Eosin (H&E) stains met the intended reactivity and predictable staining characteristics for 2 of 11 test days reviewed. The laboratory performed approximately 65 test days per year. Findings include: 1. Stain quality control (QC) records failed to include documentation H&E stain was acceptable for use on 06/29/2018 and 03/14/2019. 2. In an interview conducted on 04/05/2019 at approximately 11:15 A.M., staff confirmed stained QC was not entered in the quality control record for 06/29/2018 and 03/14/2019.

D5607

HISTOPATHOLOGY
CFR(s): 493.1273(d)(f)

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on Mohs micrographic frozen section surgery maps and reports review, lack of documentation, and confirmation by staff, the laboratory failed to ensure the person qualified to perform histopathology slide diagnosis failed to sign the Mohs maps for 2 of 11 Mohs maps reviewed. The laboratory performed approximately 65 cases per year. Findings include: 1. Mohs maps reviewed for case numbers 2018-013 on 04/26/2018 and 18-024 on 06/29/2018 failed to include the signature or initials of the qualified testing person. 2. In an interview conducted on 04/05/2019 at approximately 11:20 P.M. the laboratory staff confirmed the maps were not signed by the qualified laboratory director (a board certified dermatologist) and histopathology testing person.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on patient test records review, lack of documentation, and confirmation by staff, the laboratory testing personnel failed to follow the laboratory procedure to record the initial biopsy diagnosis on the Mohs surgical map for 2 of 11 reports reviewed, and failed to record the diagnosis for the specimen reviewed for 1 of 11 Mohs maps reviewed, and failed to record cryostat temperatures for 1 of 11 test days reviewed. The laboratory performed approximately 65 Mohs surgeries reviewed. Findings include: 1. Mohs maps reviewed failed to include the specimen site diagnosis report from the reference lab for the initial biopsy for cases 19-012 and 19-016. 2. Mohs maps reviewed failed to include the determination that the final surgical stage was clear of tumor or if tumor persists for case number 18-01 and 18-024. 3. Cryostat temperature records failed to include documentation the instrument was checked prior to testing patient frozen sections on 02/01/2019. 4. In an interview

conducted on 04/05/2019 at approximately 11:20 A.M., staff confirmed the maps were missing the final diagnosis on the map report, the signature of the qualified testing person on 2 maps, and failed to record the cryostat temperature on the record chart.