

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0540265	(X3) Date Survey Completed 03/21/2018
Name of Provider or Supplier Carson Dermatology	Street Address, City, State 1505 Medical Pkwy, Carson City, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 3/21/18. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 a sample survey of 13 random patient Mohs Maps, review of the histopathology accession logs, and review of associated histopathology slides, the laboratory failed to have an adequate system to ensure the optimum integrity of a patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: A review of 13 random patient Mohs Maps and review of the associated histopathology slides, the laboratory failed to ensure optimum integrity of a patient's specimen from the time of collection through completion of testing and reporting results. The Mohs Map for accession #17-7160 indicated that there were four slides associated with this case. Laboratory personnel found three slides for accession #17-7160. The laboratory performs approximately 9,198 histopathology tests annually.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p>

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on a sample survey of 16 random patient biopsy reports, review of the histopathology accession logs, review of associated histopathology slides, and interview with laboratory personnel, the laboratory failed to have an adequate system to ensure histopathology slide reports were saved to the patient's electronic medical record. Findings include: Review of 16 random patient biopsy reports for a sample survey revealed that for accession #16-5728B from 10/31/16, there was no histopathology report in the electronic medical record. Laboratory personnel #1 indicated during the on-site survey on 3/21/18 at approximately 4:00 PM that the laboratory was transitioning from a paper reporting system to an electronic reporting system in October 2016 and the dermatologist reading the biopsy slide may not have saved the report to the patient's medical record. The laboratory performs approximately 9,198 histopathology tests annually.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a sample survey of 16 random patient biopsy reports and 13 random patient Mohs Maps and review of associated histopathology slides and interview with laboratory personnel, the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. The laboratory did not have a quality assessment program to ensure that all histopathology reports for biopsy slides were entered into the electronic medical record system and to ensure that information on the Mohs Maps was accurate. 2. Review of 16 random patient biopsy reports for a sample survey revealed that for accession #16-5728B from 10/31/16, there was no histopathology report in the patient's electronic medical record. 3. The Mohs Map for accession #17-7160 indicated that there were four slides associated with this case. Laboratory personnel found three slides for accession #17-7160. The laboratory personnel confirmed the findings during the on-site survey on 3/21/18 at approximately 4:30 PM. The laboratory performs approximately 9198 histopathology tests annually.