

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2087718	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Keith Mark Gross Md Inc	Street Address, City, State 240 Us Hwy 95a Suite A, Fernley, 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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 8/08/18. 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.</p>
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 seven randomly selected patient Mohs Maps, review of the histopathology accession logs, and review of associated histopathology slides, and interview with the practice manager, 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 seven randomly selected patient Mohs surgery accession log entries, review of associated 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 accession log entries for one patient, accession #M12071601 for the left cheek indicated that there were three stages and three slides associated with this case and M12071604 for the same patient's mid-nose had two stages and two slides associated with this case. Laboratory personnel found two slides for accession #M12071601 and three slides for #M12071604. The practice manager stated during the on-site survey on 8/08/18 at</p>

approximately 1:15 PM that the number of stages and slides were transposed for these two accession numbers on the accession log. The laboratory performs approximately 500 histopathology tests annually.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records for twice annual accuracy checks for Mohs slides sent to a reference laboratory and interview with the practice manager, the laboratory failed to verify the accuracy of histopathology slides read for Mohs surgery at least twice annually. Findings include: A review of laboratory records for Mohs slides sent to a reference laboratory for accuracy checks from July 2016 through July 2018 found only one event where slides were sent to a reference laboratory for verification of accuracy in 2017. Two patient cases, accession # M071217-02 and # M071217-08, from 7/12/17 were sent out to a reference laboratory for the laboratory's accuracy checks. The practice manager confirmed the finding during the on-site survey on 8/08/18 at approximately 1:30 PM. The laboratory performs approximately 500 histopathology tests annually.