Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2066782	(X3) Date Survey Completed 03/12/2018
Name of Provider or Supplier La Laser Center/Murrieta Dermatology & Skin Cancer	**Street Address, City, State** 40663 Murrieta Hot Springs Rd Ste C3, Murrieta, CA	
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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems. The findings included: See D-5217 and D-6171
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 the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to ensure the accuracy of the testing procedures and evaluate the proficiency of testing performance the laboratory performed. The findings included; a. The laboratory performed histopathology in its Mohs surgery procedures. b. For histopathology testing CLIA requirements to ensure

	the accuracy of the testing procedures at least twice annually, the laboratory elected to perform peer review randomly for the testing personnel at least twice annually and document the activities. c. The laboratory director, who is not a ABD board certified dermatologist but certified by ABPS, does not satisfy the CLIA requirements pertaining to the qualifications under 42 CFR part 493. 1449 (a) (b) or (a) (l). d. Peer review of the laboratory 's histopathology testing, was not performed by qualified personnel..
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory director failed to provide overall management and direction in accordance with 493.1445 of 42 CFR part 493. The findings included: See D-6079 and D-6171
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory director failed to employ the testing personnel who are qualified to perform test procedures and assure compliance with the applicable CLIA regulations. The findings included: See D-6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that

specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to satisfy the qualification of the high complexity testing personnel who performed histopathology in Mohs surgery procedures. The findings included: a. The laboratory performed Mohs surgery procedures which including the diagnosis of histopathology. b. Among the four California State licensed physicians employed by this laboratory, listed in the

	Laboratory Personnel Report (CMS form 209), there are two American Board of Dermatology (ABD) certified dermatologists and two American Board of Physician Specialty (ABPS) certified physician to practice dermatology. c. The two physician who were certified by ABPS to practice dermatology in the laboratory did not satisfy the CLIA requirements and qualified to perform histopathology while they performed Mohs surgery. d. The CLIA regulations require the high complexity testing personnel to perform histopathology must meet 42 CFR part 493. 1449 (a) (b) or (a) (l). e. The laboratory staff affirmed (3/13/2018 @11:15 am) that these two physicians who were certified by ABPS doing Mohs procedures and performed histopathology testing did not satisfy the CLIA requirements to perform histopathology.