Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114693	01/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Radiant Dermatology And Aesthetics Pllc	22659 Highway 59 N Suite 140, Kingwood, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the 2017 and 2018 personnel records, laboratory policies, and confirmed in interview, the laboratory failed to establish policy and procedures to assess competency for 1 of 1 general supervisor, 1 of 1 technical supervisors and 1 of 1 testing personnel. Findings were: 1. Review of the laboratory records available revealed no documentation of a policy and procedure to assess competency for 1 of 1 general supervisor , 1 of 1 technical supervisor and 1 of 1 testing personnel (hire date 11/27/01). 2. An interview with the office manager on 1/8/19 at 1035 hours in the laboratory confirmed the above findings. She was unaware the laboratory was required to perform the competencies.
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 confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 1 tests in 2017 and 2018. (Mohs) Findings were: 1. A review of laboratory testing records from 2017 revealed no documentation of the laboratory verifying the accuracy for the Mohs test for 2017. 2. A review of laboratory testing records from 2018 revealed 1 of 2 documentation of the laboratory verifying the accuracy for the Mohs test for 2018. No documentation was provided for the 2nd annual accuracy assessment for 2018. 3. An interview with office manager on 1/8/19 at 1050 hours in the laboratory confirmed the above findings.
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 review of the laboratory policies, laboratory records, and confirmed in interview, the laboratory director failed to establish and maintain a quality assessment policy to identify and detect problems in the laboratory. Refer to D5217
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory director failed to ensure the laboratory established policies and procedures to assess competencies for 1 of 1 technical supervisor, 1 of 1 general supervisor, and 1 of 1 testing personnel performing Mohs histopathology testing. Refer to D5209
D8105	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(e)(f)(g) (e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results. (f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part. (g) Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the

	laboratory's CLIA certificate, in accordance with subpart R of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's Certificate of Registration, review of the 2016-2018 patient test records, and staff interview, the laboratory failed to obtain a CLIA certificate prior to performing patient samples for Mohs histopathology tests. The findings were: 1. A review of the laboratory's Certificate of Registration revealed the laboratory's certificate was issued by CMS on 03/10/17. 2. A tour of the facility on 1/8 /19 at 0955 hours revealed the laboratory stored patient slides in the nursing area. Review of the slides stored revealed the laboratory performed 37 Mohs patient testing from 10/15/16 to 3/4/17, prior to the CLIA certificate of registration effective date of 03/10/17. Patient ID RD16-01 RD16-02 RD16-03 RD16-04 RD16-05 RD16-06 RD16-07 RD16-08 RD16-09 RD16-10 RD16-11 RD16-12 RD16-13 RD16-15 RD16-16 RD16-17 RD16-18 RD17-01 RD17-02 RD17-03 RD17-04 RD17-06 RD17-07 RD17-08 RD17-09 RD17-10 RD17-11 RD17-12 RD17-13 RD17-14 RD17-15 RD17-16 RD17-17 RD17-18 RD17-19 RD17-20 RD17-21 3. An interview with the laboratory manager on 1/8/19 at 1045 hours in the office confirmed the laboratory performed Mohs patient testing prior to 3/1017. She was unaware the laboratory didn't have the correct CLIA certificate to perform Mohs testing prior to change of ownership.