Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114693	04/21/2021
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	44697 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.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory policy Quality Control Policy in section VIII, H&E Quality control (QC) logs from 5/1/2019 to 4/21/21, patient final reports, and confirmed in an interview the laboratory failed to document H&E stain quality for 4 of 20 days reviewed. The findings were: 1. Review of Quality Control policy in section VIII revealed: "A control slide will be made and evaluated each day that a frozen section is prepared. A record of the control slide will be maintained. The first slide from the first Mohs case may serve as the control slide for each day." 2. Review of H&E QC logs from 5/1/2019 to 4/21/21 revealed the laboratory failed to document H&E stain quality for 4 of 20 days. 6/24/19 7/29/19 9/16/19 4/9/21 3. Random review of patient reports from 5/1/2019 to 4/21/21 revealed the laboratory performed the following 7 patients with no documentation of the H&E stain quality. 6/24/19 Case# 179 and Case# 183 7/29/19 Case# 221 9/16/19 Case# 282 and Case# 285 4/9/21

	Case# 125 4. An interview with the practice manager on 4/21/21 at 11:00am in the office confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the temperature and humidity log from 2020, patient test records, and confirmed in an interview, the laboratory failed to document corrective action for out of range humidity for 1 of 43 days reviewed. The findings were: 1. Review of Microtome Cryostat HM 520 Instruction manual (D-69190) revealed the operating condition for humidity is "at a max. rel. humidity of 60%". 2. Review of temperature and humidity log in 2020 revealed the humidity should not be greater than 60%. 3. Review of temperature and humidity log in 2020 revealed 1 of 43 days humidity was out of the acceptable range. 7 /13/20 Humidity recorded as 68% 4. Review of the lab records from the above date revealed no documentation of corrective action. 5. Review of patient logs for 7/13/20 revealed 9 patients were performed. 7/13/20 Case# 201 7/13/20 Case# 202 7/13/20 Case# 203 7/13/20 Case# 204 7/13/20 Case# 205 7/13/20 Case# 206 7/13/20 Case# 207 7/13/20 Case# 208 7/13/20 Case# 209 6. An interview with practice manager on 4 /21/21 at 11:30am in the office confirmed the above findings.