

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2114693	(X3) Date Survey Completed 11/18/2024
Name of Provider or Supplier Radiant Dermatology And Aesthetics Pllc	Street Address, City, State 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	An announced survey of the laboratory was conducted on 11/18/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview, review of laboratory's policies/procedures, temperature records and annual case volumes, the laboratory failed to ensure temperature and humidity for storage/preservation of patient specimen slides was defined and monitored for one of one slide storage area used by the laboratory. Findings included: 1. In an interview on 11/18/2024 at 1000 hours in the breakroom the laboratory's histotechnologist stated that patient specimen slides were stored at the nursing station area. She also indicated that the area was not monitored for temperature or humidity to ensure slide preservation. 2. Review of laboratory's policies/procedures revealed the laboratory did not have in place protocols defining required temperature/humidity for storage of patient specimen slides to ensure their preservation. 3. Review of laboratory's temperature/humidity records revealed there was no documentation of environmental monitoring for the patient specimen slide storage area. 4. Review of laboratory's annual case volumes for 2023 revealed the laboratory performed testing on patient sample slides for 622 cases annually. 5. In an interview on 11/18/2024 at 1030 hours in the office, the facility's Practice Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.</p>
D5781	CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, temperature monitoring records and staff interview, the laboratory failed to document corrective action for 8 of 8 instances corrective action was required for out-of-range temperatures in 2023 and 2024. Findings included: 1. Review of laboratory's policy "Mohs Surgery" (last reviewed 2024) revealed: "Temperature should be obtained and recorded on a daily basis. Temperature variations beyond specified ranges should be reported to laboratory director and corrective action taken, which may include notifying building maintenance for adjustments. - The Mohs laboratory temperature should be within the range of 60-75 degrees fahrenheit(sic) (15-23 degrees celsius(sic))" 2. Review of laboratory's temperature logs revealed: "Temperature should not be greater than 80 and no less than 50." The temperature range on the log did not match the temperature range requirements in the laboratory's procedure/policy. 3. Review of laboratory's temperature records for 2023 and 2024 revealed the following out-of-range temperatures for which corrective action was not documented: Date: Temperature (degrees Fahrenheit) 06/26/2023 80.2 07/31/2023 95.8 08/07/2023 82.1 08/28/2023 80.8 09/11/2023 79.6 06/24/2024 80.1 06/28/2024 82.4 07/29/2024 80.1 4. The laboratory was asked to provide corrective action documentation for the above out-of-range temperatures and no such documentation was available for review prior to survey exit. 5. In an interview on 11/18/2024 at 1030 hours in the office, the facility's Practice Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.