Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2218613	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Radiant Dermatology & Aesthetics Pllc	9240 N Sam Houston Pkwy East, Suite 201, Humble, 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 in compliance with applicable CLIA Conditions, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, review of laboratory's temperature and humidity logs and staff interview, it was determined the laboratory failed to define and monitor storage conditions for proper preservation of processed histopathology slides. Findings included: 1. Review of laboratory's policies and procedures revealed the laboratory did not have protocols in place defining storage conditions to ensure proper preservation of processed slides. 2. Review of laboratory's temperature and humidity logs revealed the laboratory did not have temperature /humidity monitoring logs for the histopathology slides' storage room. 3. In an interview on 03/09/2023 at 0950 hours in the laboratory, the facility's Practice Manager (as identified on the facility's Entrance Conference documentation)

	confirmed that the laboratory was not monitoring storage conditions of the histopathology slides.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of the laboratory's random patient MOHS surgery records, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to ensure the retained copies of grossing records included evidence of the performing personnel's identifiers or signature for 2 of 2 reports reviewed. Findings included: 1. Review of the laboratory's random patient MOHS surgery records revealed 2 of 2 reviewed records did not document evidence of the performing personnel's identifiers or signature. These were: Case: AJ23-035 Date: 02/15/2023 No grossing personnel's signature or identifier was documented on the retained copy of the MOHS surgery grossing map. Case: AJ23-036 Date: 02/15/2023 No grossing personnel's signature or identifier was documented on the retained copy of the MOHS surgery grossing map. 2. Review of the laboratory's policies and procedures revealed there was no protocol in place for ensuring documentation of identifiers or signatures of the personnel performing grossing on patient MOHS surgery records/maps. 3. In an interview on 03/09/2023 at 1045 hours in the office, the facility's Practice Manager (as identified on the facility's Entrance Conference documentation), after review of the data, confirmed the findings.
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 the laboratory's Cryostat temperature records for October to December of 2022, review of laboratory's corrective action records and staff interview it was determined the laboratory failed to document corrective action for 1 of 23 reviewed Cryostat temperatures when temperature was documented out of laboratory defined range. Findings included: 1. Review of the laboratory's Cryostat temperature logs revealed: "Temperature should be maintained at -21C to -35C. Any change in range should be reported to the lab director and documented." 2. Further review of the laboratory's Cryostat temperature records for October to December of 2022 revealed

	the following 1 of 23 temperatures was documented outside of laboratory defined range: Date: Temperature: 10/14/2022 -20C There was no documentation of change in temperature range or notification to lab director. 3. Review of laboratory's corrective action records revealed no documentation of corrective action for the out of range temperature. 4. In an interview on 03/09/2023 at 1000 hours, the facility's Practice Manager (as identified on the facility's Entrance Conference documentation), after review of the data, confirmed the findings.