Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2148273	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Braun Dermatology & Skin Cancer Center	5911 Kingstowne Village Parkway, Suite 100, Alexandria, VA	

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 CLIA Recertification survey was conducted at the Braun Dermatology & Skin Cancer Center on 07/13/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), daily laboratory Quality Control (QC) and Quality Assurance (QA) records, lack of documentation, daily patient test log, and interview, the lab failed to retain the daily laboratory temperatures, hematoxylin and Eosin (H&E) reagent monitoring, instrument and laboratory cleaning and maintenance records, and the monthly lab director QC review logs for the calendar year 2021 (12 months) while reporting 473 patients. Findings include: 1. Review of the P&P revealed QC and QA instructions for completing daily logs for the following: Daily H&E Stainer Reagent Monitoring; daily laboratory room, humidity, and refrigerator temperature monitoring; daily cryostat temperature, cleaning and maintenance monitoring; daily microscope cleaning and maintenance monitoring; and daily laboratory cleaning monitoring. In addition, the review revealed the following statement, "2.2- Quality Assurance Review with Staff- the laboratory director will review, on a monthly basis, the results of the daily quality assurance logs, and determine ways in which the laboratory can improve the quality of its work." 2. The review of available aforementioned QC and QA records revealed lack of documentation for the calendar year 2021 (12 months). The following logs were not

	available for review: Daily Hematoxylin and Eosin (H&E) Stainer Setup, Daily Cryostat cleaning and maintenance log, daily cryostat temperature log, daily laboratory cleaning and maintenance log, daily laboratory refrigerator log, daily histotech microscope cleaning maintenance log, daily laboratory temperature and humidity log, and the lab director QC monthly review log. During an interview with the histotech on 07/13/22 at approximately 11:20 AM, the inspector requested to review the aforementioned records. The histotech searched for the records and stated, "I apologize, the records should be in the file cabinet in a folder and I cannot locate them." 3. Review of the daily patient testing log revealed 473 patients reported for Mohs surgical histology tissue examinations in 2021. 4. An exit interview with the laboratory director on 07/13/22 at noon confirmed the findings.