Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1031013	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Center Of Northern Virginia	19465 Deerfield Ave, Ste 401, Lansdowne, 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 Skin Cancer Center of Northern Virginia on February 14, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the laboratory's temperature records, manufacturer requirements, lack of documentation, and interview, the lab failed to monitor and document the room temperatures for eighteen (18) of 18 Mohs surgery days reviewed from November 1, 2021 until November 30, 2021. Findings include: 1. Review of laboratory's temperature log records revealed a lack of documentation of room temperature recordings for the following Mohs surgery days from November 1, 2021 until November 30, 2021: 11/1/2021, 11/2/2021, 11/4/2021, 11/5/2021, 11/8/2021, 11/9/2021, 11/10/2021, 11/11/2021, 11/12/2021, 11/15/2021, 11/16/2021, 11/17/2021, 11/18/2021, 11/19/2021, 11/22/2021, 11/23/2021, 11/29/2021 and 11/30/2021. Total of 18 of 18 days reviewed. The surveyor requested to review documentation of the room temperature for the above listed 18 days. The laboratory provided no documentation to review. 2. Review of the Avantik QS 11 Cryostat Product manual revealed the required Operating Temperature of +5C to +35C (+41F to +95F). 3. In an exit interview with the Laboratory Director and Office Manager on February 14, 2023 at approximately 11:00 AM, the above findings were confirmed.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, 2021 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), quality assurance documentation, lack of documentation, and an interview, the laboratory director (LD) failed to ensure the laboratory followed an established LD approved corrective action plan to ensure documentation/retention of twice annual verification of Histopathology accuracy for calendar year 2022. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Frequency and Record of Quality Control Analyses", that stated "Two cases of Mohs surgery will be sent to the outside laboratory per year. These cases will be reviewed, and the results recorded on the appropriate QC form." 2. Review of the laboratory's previous CMS-2567 POC (LD signed 6/1/2021) revealed a corrective action plan to ensure documentation/retention of the twice annual verification of Histopathology accuracy that stated "Why: This was an inadvertent oversight...How/what: This deficiency will be corrected by having our proficiency testing done June of every year. This will give the lab plenty of time to make adjustments before the end of the year. Who: The Lab director is responsible to see that this takes place." 3. Review of the laboratory's quality assurance documentation revealed twice annual verification of Histopathology accuracy during calendar year 2021 and a lack of documentation of the twice annual verification of Histopathology accuracy during calendar year 2022. The surveyor requested to review documentation of the twice annual verification of Histopathology accuracy during calendar year 2022. The laboratory provided no documentation for review. 4. In an exit interview with the Laboratory Director and Office Manager on February 14, 2023 at approximately 11:00 AM, the above findings were confirmed.