Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1002070	(X3) Date Survey Completed 01/26/2022
Name of Provider or Supplier Clinical Skin Center Of Northern Virginia, The	**Street Address, City, State** 3700 Joseph Siewick Drive - Suite 404, Fairfax, 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 off-site CLIA recertification survey was conducted for The Clinical Skin Center of Northern Virginia on January 26, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on January 7, 2022 and virtual record review conducted on January 21 and 24, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's "Chemical Log Sheet", MOHS/Frozen Section accession log and interview, the laboratory failed to ensure the Schiff's Reagent used in the staining of frozen section specimens was within manufacturer's expiration date while staining nine (9) patients from August 13, 2021 until August 27, 2021. Findings include: 1. A review of the laboratory's "Chemical Log Sheet" revealed the following: a. 1 gallon of Mercedes Schiff's reagent (lot number 103203 /expiration date 07/31/2021) was received on 11/05/2020 with an open date of 05/28 /2021; b. 1 gallon of Mercedes Schiff's reagent (lot number 2116916/expiration date 06 /22/2022) was received on 08/26/2021 with an open date of 09/03/2021. There were no other lots of Schiff's reagent listed with "Open Dates" on the laboratory's "Chemical Log Sheet". 2. A review of the laboratory's "MOHS/Frozen Section Accession Log" revealed 9 Frozen Section patient specimens were stained from 08/01 /2021 until 09/03/2021 while using the expired Schiff's reagent (lot number 103203 /expiration date 7/31/2021). 3. In an exit interview with Mohs Technician A on January 26, 2022 at approximately 10:00 AM, the findings were confirmed. B. Based

	on a review of the laboratory's "Chemical Log Sheet", MOHS/Frozen Section accession log, and interview, the laboratory failed to ensure the 10% Potassium Hydroxide (KOH) solution used for the softening of patient nail specimens was within manufacturer's expiration date while processing six (6) patient specimens from October 29, 2021 until November 19, 2021. Findings include: 1. A review of the laboratory's "Chemical Log Sheet" revealed the following: a. 1 bottle of Mercedes 10% KOH solution (lot number 9301/expiration date 10/28/2021) received on 03/23 /2020 with an open date of 01/08/2021; b. 1 bottle of Mercedes 10% KOH solution (lot number 0275/expiration date 10/01/2022) received on 01/26/2021 with an open date of 11/19/2021. There were no other lots of KOH solution listed with "Open Dates" on the laboratory's "Chemical Log Sheet". 2. A review of the laboratory's "MOHS/Frozen Section Accession Log" revealed six (6) nail specimens were processed from 10/29/2021 until 11/19/2021 with the expired 10% KOH solution (lot number 9301/expiration date 10/28/2021). 3. In an exit interview with Mohs Technician A on January 26, 2022 at approximately 10:00 AM, the findings were confirmed.