Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2131521	09/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Specialists Pllc	17510 W Grand Pkwy S Ste 420, Sugar Land, 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 09/25/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories. STANDARD LEVEL DEFICIENCIES were cited. .
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observations and staff interview, the laboratory failed to label secondary containers for 15 of 15 vessels with stain/alcohol reagents used in Mohs testing. Findings included: 1. Surveyor's observations on 09/25/2023 at 0915 hours in the laboratory revealed 15 unlabeled containers as follows: a. 14 containers of solutions on the stainer used in Hematoxylin and Eosin staining b. One bottle of clear solution stored atop the Avantic Cryostat 2. In an interview on 09/25/2023 at 0955 hours in the laboratory, the facility's Regional Manager (as indicated on submitted Survey Entrance/Exit Conference document), after review of the containers, confirmed the findings.
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: Based on surveyor's observations, laboratory's test volumes and staff interview, the laboratory failed to ensure reagents were not used beyond their expiration date for one of one container of Hematoxylin stain solution in use. Findings included: 1. Surveyor's observations on 09/25/2023 at 0930 hours in the laboratory revealed one half-full container of Hematoxylin Stain Solution, Gill III (Lot 211331; received 08/10 /2021; opened 03/02/2022) stored in the flammable cabinet, which expired on 2023-05-19. This was the only evident container of Hematoxylin solution in the laboratory. 2. Review of laboratory's test volumes revealed the laboratory performed stains on approximately 1000 samples each year. 3. In an interview on 09/25/2023 at 0955 hours in the laboratory, the facility's Regional Manager (as indicated on submitted Survey Entrance/Exit Conference document), after review of the Hematoxylin solution, confirmed the findings.