

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2229631	(X3) Date Survey Completed 05/16/2022
Name of Provider or Supplier Skin Care Specialists, PLLC	Street Address, City, State 23050 Westheimer Parkway, Katy, 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 was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's Humidity and Temperature Logs from 2022, surveyor observation, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to have a mechanism in place to monitor the humidity of the laboratory for six of six days from February to May 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Program' revealed the following: "The environment in the working area of the laboratory will be controlled by commonly used heating, air-conditioning and ventilation equipment used throughout the entire medical office, which will maintain at a working temperature of 50 -80 degrees Fahrenheit, and humidity of less than 60%." 2. A review of the laboratory's Humidity and Temperature Logs from 2022 revealed the laboratory documented the humidity at 30% for the following 6 days from February to May 2022: 2/11/22 3/11/22 3/25/22 4/9/22 *Documented on the wrong date, patient's specimens were processed on 4/8/22 4/22/22 5/6/22 3.</p>

Surveyor observation of the laboratory on 5/16/22 at 9:30 revealed the laboratory used the thermostat to document the room temperature of the laboratory. Further observation of the laboratory revealed there was no humidity monitor and the thermostat did not measure the humidity of the room. 4. A random review of the laboratory's patient test records revealed the following 12 patient's specimens were processed when the laboratory's humidity was not being monitored: Patient: TF22-K001 Date: 2/11/22 Patient: TF22-K006 Date: 2/11/22 Patient: TF22-K012 Date: 3/11/22 Patient: TF22-K015 Date: 3/11/22 Patient: TF22-K018 Date: 3/25/22 Patient: TF22-K021 Date: 3/25/22 Patient: TF22-K028 Date: 4/8/22 Patient: TF22-K031 Date: 4/8/22 Patient: TF22-K036 Date: 4/22/22 Patient: TF22-K039 Date: 4/22/22 Patient: TF22-K041 Date: 5/6/22 Patient: TF22-K044 Date: 5/6/22 5. An interview with the MOHS histotech on 5/16/22 at 9:30 a.m. in the laboratory, after review of the records, confirmed the above findings.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of laboratory's policies, the laboratory's H&E and QC Stain Logs from 2022, a review of patient test records, and staff interview, it was revealed that the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for MOHS histopathology slides each day of use for one of six days reviewed from February to May 2022. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment Manual' revealed the following: "Quality control is performed for the adequacy of staining. A daily control slide for H&E stain is documented representing stain quality for each day of use." 2. A review of the laboratory's H&E and QC Stain Logs from February to May 2022 revealed no documentation of the intended reactivity for the H&E stain on April 8, 2022. 3. A review of patient test records revealed the following 8 patients were tested on April 8, 2022 when the intended reactivity of the H&E slide was not documented: Patient Case Numbers: 025, 026, 027, 028, 029, 030, 031, 032 4. An interview with the MOHS histotech on 5/16/22 at 9:40 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: QC = Quality Control