

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2177989	<b>(X3) Date Survey Completed</b> 06/02/2025
<b>Name of Provider or Supplier</b> Skin Care Specialists, PLLC	<b>Street Address, City, State</b> 9225 Katy Freeway, Ste 404, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and (re)certification is recommended. Standard level deficiencies were cited.
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the Microscope Maintenance Records, patient test records, and staff interview, the laboratory failed to have documentation of performing the daily microscope maintenance procedures for five of eight days from September 2024 to April 2025. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Program' revealed the following: "Equipment Quality Control- Microscope 1. Microscope stage and ocular eyepieces are to be cleaned daily. Stage is to be cleaned with alcohol or similar cleaner and ocular eyepieces are to be cleaned with lens paper. - Every action is documented on the maintenance record form." 2. A review of the Microscope Maintenance Records from September 2024 to April 2025 revealed the laboratory failed to have documentation of performing the daily microscope maintenance procedures for the following 5 days: 9/25/24 11/27/24 12/17/24 2/26/25 3/26/25 3. A review of patient test records revealed the following patients were tested on days when the daily microscope maintenance procedures were not documented: Date tested: 9/25/24 Patient Case Numbers: TF24-M064 through TF24-M073 Date tested: 11/27/24 Patient Case Numbers: TF24-M081 through TF24-M088 Date tested: 12/17/24 Patient Case Numbers: TF24-M089 through TF24-M098 Date tested: 2/26/25 Patient Case Numbers: TF25-M001 through</p>

TF25-M010 Date tested: 3/26/25 Patient Case Numbers: TF25-M011 through TF25-M020 4. In an interview on 6/2/25 at 10:15 a.m. in the laboratory, after review of the records, the regional manager confirmed the above findings.

**D5473**

**CONTROL PROCEDURES**

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

(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.

This STANDARD is not met as evidenced by:  
Based on a review of laboratory's policies, the laboratory's H&E and QC Slide Logs, patient test records, and staff interview, the laboratory failed to document the intended reactivity of the H&E (hematoxylin and eosin) stain for MOHS histopathology slides each day of use for two of four days in February and March 2025. Findings include: 1. A review of the laboratory's policy titled 'MOHS Laboratory Procedure Manual Histopathology- MOHS Surgery' revealed the following: "A daily control slide for H&E stain is documented representing stain quality for each date of use." 2. A review of the laboratory's H&E and QC Slide Logs from February and March 2025 revealed the laboratory failed to have documentation of the intended reactivity for the H&E stain on the following 2 days: 2/26/25 3/26/25 3. A review of patient test records revealed the following patients were tested on days when the intended reactivity of the H&E slide was not documented: Date tested: 2/26/25 Patient Case Numbers: TF25-M001 through TF25-M010 Date tested: 3/26/25 Patient Case Numbers: TF25-M011 through TF25-M020 4. In an interview on 6/2/25 at 10:20 a.m. in the laboratory, after review of the records, the regional manager confirmed the above findings.