

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2149971	(X3) Date Survey Completed 04/24/2026
Name of Provider or Supplier Skin Care Specialists, PLLC	Street Address, City, State 1501 River Pointe Drive Ste 150, Conroe, 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 04/24/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer instructions, laboratory's policies/procedures, humidity records, Remedial action logs, and staff interview, the laboratory failed to document corrective action for out-of-range humidity for 38 of 38 instances corrective action was required from July 2024 through December 2025. Findings included: 1. Surveyor's observations on 04/24/2025 at 1200 hour in the laboratory revealed the laboratory had one operational Leica CM 1860 Cryostat in use. 2. Review of the manufacturer instructions "Leica CM1860 UV Cryostat" (version 2.5, Revision S-11.2021) revealed: "Relative humidity (operation) 20 to 60 % [percent] RH non-condensing" 3. Review of laboratory's policy "Quality Control Program" (last reviewed by laboratory director on 07/16/2024) revealed: "Any remedial action taken by the laboratory will be documented on a Remedial action log</p>

form and reviewed by the Laboratory Director." 4. Review of laboratory's Humidity and Temperature Logs revealed: "3. Humidity levels are to be no greater than 60 percent." 5. Review of laboratory's Humidity and Temperature Logs from July 2024 through December 2025 revealed the following 38 of 38 days the humidity was recorded out of range without documentation of corrective action: Date: Humidity (%): 70/10/2024 61 07/11/2024 67 07/12/2024 62 07/19/2024 63 07/24/2024 62 07/25/2024 62 07/26/2024 63 07/31/2024 61 08/01/2024 62 08/07/2024 61 08/08/2024 62 08/09/2024 64 08/13/2024 63 08/16/2024 61 08/20/2024 61 08/30/2024 64 09/04/2024 64 09/10/2024 62 09/11/2024 62 09/12/2024 62 09/13/2024 62 09/20/2024 62 09/21/2024 61 09/24/2024 62 09/25/2024 63 09/26/2024 62 10/01/2024 61 10/02/2024 62 10/03/2024 61 02/05/2025 61 02/06/2025 61 02/07/2025 61 03/25/2025 85 04/02/2025 62 04/03/2025 62 04/04/2025 63 05/02/2025 61 07/08/2025 72 6. The laboratory was asked to provide Remedial action logs for the above out of range humidity instances and none were available for review prior to survey exit. 7. In an interview on 04/24/2026 at 1310 hours in the breakroom, the laboratory's Histotech (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.

D6080

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies/procedures, laboratory's records and staff interview, the laboratory director failed to define protocols/requirements for documentation of laboratory director's on-site visits, and to document two of two required visits in 2025. Findings included: 1. Review of laboratory's policies /procedures revealed the laboratory did not have protocols in place defining the requirements of laboratory director's on-site visits, including performing activities that are part of the laboratory director responsibilities, or how the visits were to be documented. 2. Review of laboratory's records revealed the laboratory did not have documentation of laboratory director's on-site visits, including documentation of fulfillment of laboratory director's responsibilities, for two of two visits required in 2025. 3. In an interview on 04/24/2026 at 1250 hours in the breakroom, the laboratory's Histotech (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.