Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2149971	06/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Specialists, Pllc	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 06/27/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, proficiency testing (PT) records and staff interview, the laboratory failed to document 1 of 4 PT records reviewed on a semi-annual basis as per its own policy. Findings included: 1. Review of laboratory's policy "Proficiency Testing" (last reviewed July 2023) revealed: "Semi-annually, the tech will send three cases containing the original slides and corresponding Mohs maps out for microscopic examination by a Board Certified Pathologist." 2. Review of laboratory's PT records revealed the following dates PT material was sent out for examination: 12/21/2022 Shipment contained cases from 2nd half of 2022 12/22/2023 Shipment contained cases from 1st half of 2023 01/10/2024 Shipment contained cases from 2nd half of 2023 06/19/2024 Shipment contained cases from 1st half of 2024 There was no semi-annual shipment of cases for review between December of 2022 and December of 2023. 3. In an interview on 06/27/2024 at 1340 hours in the break room, the facility's CEO (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: This is a repeat deficiency from 08/09/2022. Based on review of laboratory's policies and procedures, review of laboratory's Microscope Maintenance records for January to May of 2024 and staff interview, the laboratory failed to document monthly grounding checks for 5 of 5 months reviewed, as per its own policy. Findings included: 1. Review of laboratory's policy "Quality Control Program" (last reviewed by laboratory director in July of 2023) revealed: "EQUIPMENT QUALITY CONTROL - MICROSCOPE ...2. Grounding check is monitored monthly. ...4. Each action is documented on the maintenance record form." 2. Review of the laboratory's Microscope Maintenance records for January to My of 2024 revealed there was no documentation of monthly grounding checks for the following 5 of 5 reviewed months: January 2024 February 2024 March 2024 April 2024 May 2024 3. The laboratory was asked to provide the monthly grounding check documentation and no such documentation was available for review. 4. In an interview on 06/27/2024 at 1415 hours in the break room, the facility's CEO (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: This is a repeat deficiency from 08/09/2022. Based on review of laboratory's policies /procedures, H&E (hematoxylin and eosin) Stain quality control (QC) records and staff interview, the laboratory failed to document lot numbers/expiration dates of H&E Stain reagents in use for 5 of 5 months reviewed from January to May 2024. Findings included: 1. Review of laboratory's policy "Quality Control Program" (last reviewed by laboratory director in July of 2023) revealed there was no mention of requirements for quality control or documentation requirements for the H&E Stain acceptability or reagent lot/expiration dates. 2. Review of the laboratory's H&E Stain QC records for January to May 2024 revealed the laboratory did not document lot numbers or expiration dates of each of the H&E Stain reagents in use for each of the 5 months reviewed. 3. In an interview on 06/27/2024 at 1415 hours in the break room, the facility's CEO (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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. This STANDARD is not met as evidenced by: Based on review of the manufacturer instructions, review of laboratory's temperature and humidity logs for January to June of 2024 and staff interview, the laboratory failed to document corrective actions for 14 of 14 instances where humidity was out of manufacturer's required range for operation of the Avantik QS12 Cryostat. Findings included: 1. Review of the laboratory's QS12 Cryostat Instruction Manual (Avantik 388159 - English) revealed: "Environmental specifications ... Relative Humidity Max. 60% RH up to 35C" 2. Review of laboratory's Temperature and Humidity Log's instructions revealed: "Humidity and Temperature Log >60% (percent) 50'-80'(degrees)" And, " ...3. Humidity levels are to be no greater than 60 percent." The range and instructions contraindicated the requirements for humidity. 3. Review of laboratory's temperature and humidity logs for January to June of 2024 revealed the following 14 of 14 out-of-range humidity records did not have corrective action documentation: Date: Humidity (%): 04/09/2022 68 04/10/2022 68 04/11/2022 62 04/15/2022 63 04/16/2022 64 04/17/2022 63 04/18/2022 64 05/06/2022 61 05/07 /2022 61 05/14/2022 61 05/17/2022 61 05/21/2022 61 05/30/2022 61 06/06/2022 61 4. The laboratory was asked to provide corrective action documentation for each instance of out-of-range humidity and no such documentation was available for review. 5. In an interview on 06/27/2024 at 1345 hours in the break room, the facility's CEO (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings. Key: CEO = Chief Executive Officer