Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2149971	08/09/2022
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: A. Based on review of laboratory's policies and procedures, review of the laboratory's Cryostat Maintenance records for January to July 2022 and staff interview it was determined the laboratory failed to document 4 of 7 monthly defrost activities and 7 of 7 monthly air filter cleanup activities as per laboratory's protocols. Findings included: 1. Review of laboratory's Quality Control policy (last reviewed by laboratory director

	in July of 2022) revealed: "EQUIPMENT QUALITY CONTROL - CRYOSTAT ...7. Air filter is cleaned as part of the maintenance every month. ...9. The moving components of the cryostat are oiled as recommended by the manufacturer, every 3 months or as needed. ...13. Every action is documented on the maintenance record form." 2. Review of the laboratory's Cryostat Maintenance form revealed: "4. Monthly defrost - machine should be brought down on a monthly basis to be completely cleaned out and oiled" 3. Review of the laboratory's Cryostat Maintenance records for January to July of 2022 revealed the documentation was missing monthly defrost and air filer cleanup activities as follows: January 2022 No documentation of monthly air filter cleanup February 2022 No documentation of monthly defrost No documentation of monthly air filter cleanup March 2022 No documentation of monthly air filter cleanup April 2022 No documentation of monthly air filter cleanup May 2022 No documentation of monthly defrost No documentation of monthly air filter cleanup June 2022 No documentation of monthly defrost No documentation of monthly air filter cleanup July 2022 No documentation of monthly defrost No documentation of monthly air filter cleanup 4. In an interview on 08/09/2022 at 1035 hours in the staff room, the facility's Histotechnologist, after review of the data, confirmed the findings. B. Based on review of laboratory's policies and procedures, review of laboratory's Microscope Maintenance records for January to July of 2022 and staff interview it was determined the laboratory failed to document weekly grounding checks for 7 of 7 months reviewed. Findings included: 1. Review of laboratory's policy Quality Control policy (last reviewed by laboratory director in July of 2022) 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 July of 2022 revealed there was no documentation of weekly grounding checks for the following 7 of 7 reviewed months: January 2022 February 2022 March 2022 April 2022 May 2022 June 2022 July 2022 3. The laboratory was asked to provide the monthly grounding check documentation and no such documentation was available for review prior to survey exit. 4. In an interview on 08/09/2022 at 1035 hours in the staff room, the facility's histotechnologist, after review of the data, 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: A. Based on review of the laboratory's H&E (hematoxylin and eosin) stain quality control (QC) records for January to July of 2022, surveyor's observations on 08/08 /2022 at 1030 hours in the laboratory and staff interview, it was determined the laboratory failed to document lot numbers and expiration dates for 5 of 5 stain reagents in use. Findings included: 1. Review of the laboratory's H&E stain QC records for January to July of 2022 revealed there was no documentation of reagent's lot numbers or expiration dates for 5 of 5 reagents in use. 2. Surveyor's observations on 08/08/2022 at 1030 hours in the laboratory revealed the following H&E stain reagents in use: Reagent: Gill 3 Hematoxylin Lot: 145319 Expiration date: 2023-09-30 Reagent: Eosin-Y Alcoholic 0.25% Lot: 145871 Expiration date: 2024-03-31 Reagent: 100% Reagent Alcohol Lot: 147064 Expiration date: 2024-04-30 Reagent: High DEF 1% Lot: 145328 Expiration date: 2025-03-31 Reagent: Vintage Bluing Lot:

	143917 Expiration date: 2025-02-28 3. In an interview on 08/09/2022 at 1045 hours in the staff room, the facility's histotechnologist, after review of the data, confirmed the findings. B. Based on surveyor's observations on 08/08/2022 at 1030 hours in the laboratory and staff interview, it was determined the laboratory failed to document open dates on 4 of 5 H&E (hematoxylin and eosin) stain reagents in use. Findings included: 1. Surveyor's observations on 08/08/2022 at 1030 hours in the laboratory revealed the following 4 of 5 stain reagents in use did not have docuentation of opened dates: Reagent: Gill 3 Hematoxylin Lot: 145319 Expiration date: 2023-09-30 Received: 04/15/2022 Reagent: Eosin-Y Alcoholic 0.25% Lot: 145871 Expiration date: 2024-03-31 Received: 04/15/2022 Reagent: High DEF 1% Lot: 145328 Expiration date: 2025-03-31 Received: 04/15/2022 Reagent: Vintage Bluing Lot: 143917 Expiration date: 2025-02-28 Received: 04/15/2022 2. In an interview on 08/09 /2022 at 1045 hours in the laboratory, the facility's histotechnologist confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's Cryostat Instruction Manual, review of laboratory's temperature and humidity logs for January to July of 2022 and staff interview, it was determined the laboratory failed to document corrective actions for 16 of 16 records where humidity was out of manufacturer's required range. Findings included: 1. Review of the laboratory's QS12 Cryostat Instruction Manual (Avantik 388159 - English) revealed: Page 12 "Environmental specifications ... Relative Humidity Max. 60% RH up to 35C" 2. Review of laboratory's Temperature and Humidity Log's instructions revealed: " ...3. Humidity levels are to be no greater than 60 percent." 3. Review of laboratory's temperature and humidity logs for January to July of 2022 revealed the following 16 of 16 out-of-range humidity records did not have corrective action documentation: Date: Humidity (%): 03/07/2022 60.6 04/20 /2022 62.2 05/18/2022 62.3 05/21/2022 68.2 06/01/2022 70.9 06/03/2022 60.7 07/01 /2022 60.3 07/06/2022 64.6 07/13/2022 73.5 07/15/2022 63.8 07/18/2022 67.1 07/20 /2022 67.9 07/22/2022 69.9 07/23/2022 65.4 07/29/2022 69.7 07/30/2022 64.3 4. The laboratory was asked to provide corrective action documentation for the out-of-range humidity and no such documentation was provided prior to survey exit. 5. In an interview on 08/09/2022 at 1015 hours in the laboratory, the facility's histotechnologist confirmed the findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the laboratory's Quality Assessment records for January to July of 2022 and staff interview, it was determined the laboratory failed to document quality assessment activities as per protocol for 7 of 7 months reviewed. Findings included: 1. Review of the laboratory's Quality Assessment Manual policy (last reviewed by the laboratory director in July of 2022) revealed: " It is the policy of this laboratory to apply the principles of the QA (Quality Assurance) program to all activities of the laboratory, including pre-analytic, analytic and post analytic activities." And "QUALITY CONTROL ASSESSMENT The Laboratory Director reviews all quality control charts and logs on at least a monthly basis." And "QUALITY ASSESSMENT RECORDS The American Academy of Dermatology suggests that all quality assessment records be maintained for a period of two years..." 2. Review of the laboratory's Quality Assessment records for January to July of 2022 revealed no documentation of monthly quality assessment for 7 of the 7 months reviewed. 3. The laboratory was asked to provide documentation of Quality Assessment and Laboratory Director' s QC review, and no such documentation was available for review prior to survey exit. 4. In an interview on 08 /09/2022 at 1020 hours in the staff room, the facility's histotechnologist, after review of the data, confirmed the findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of laboratory's Quality Assessment (QA) records for January to July of 2022 and staff interview it was determined the Laboratory Director failed to ensure QA was maintained and could identify failures in quality as they occur. Refer to D5793.