Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1032562	09/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Specialty Physicians Llc	1447 York Road Suite 301, Lutherville, MD	

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
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure, PT documentation, and interview with the histology technician (HT) and laboratory director (LD), the laboratory failed to ensure that PT was performed at least twice annually for each person listed on the "Laboratory Personnel Report (CLIA)" form. Findings: 1. The external PT procedure states that the technician will randomly select two slides every six months to be sent out to the Institute of Dermatopathology for evaluation. The external review of the slides documents the proficiency of the testing person evaluating the Moh's slides. 2. The PT documentation shows that only one of the two testing personnel listed on the "Laboratory Personnel Report (CLIA)" form were having slides sent out for review every six months. 3. During an interview on 09/27 /2023 at 12:20 PM, the HT and LD confirmed that external PT was not being completed on both of the testing personnel listed on the "Laboratory Personnel Report (CLIA)" form.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the policies and procedures, prepared slides, and interview with the histology technician (HT), the laboratory's procedure manual failed to include written instructions for relabeling the glass slides with a paper "shamrock" adhesive label once the slide had been reviewed by the Moh's surgeon. Findings: 1. The labeling procedure requires the slide to be labeled with the first initial of the first and last name of the patient, slide identification number, and stage. 2. Fourteen slides were reviewed. Each of the slides had a paper "shamrock" label on it. The completed slides were labeled with the complete spelling of the last name of the patient, slide identification number, and stage. Under the paper "shamrock" label the slides that were labeled with the first initial of the first name and complete spelling of the last name, slide identification number, and stage. 3. During the survey on 09/27/2023 at 12:20 AM, the HT confirmed that the procedure manual did not include an accurate description of the labeling of the slides initially and after the slides were reviewed. II. Based on review of the "Special Staining Melanoma Log", policies and procedures, and interview with the histology technician (HT), the laboratory's procedure manual failed to include the updated temperature for the slide warmer. Findings: 1. The "Special Staining Melanoma Log" showed that the recorded temperature for the slide warmer was recorded as 34.5 on 12/07/22 and then on 12/14/22 the temperature was recorded as 30. 2. The HT stated that the sales representative from the special stain company had visited the office and was helping the laboratory trouble shoot some problems they were having with the staining. The sales representative suggested that the temperature on the slide warmer be lowered to 30. 3. The HT stated that the procedure manual did not list the temperature that the slide warmer was to be set at when preparing the special stain slides. 4. During the survey on 09/27/2023 at 12:20 AM, the HT confirmed that the procedure manual had not been updated with the new setting for the slide warmer after the changes had been made and approved by the laboratory director.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation of the staining station in the histology laboratory and interview with the histology technician (HT), the laboratory failed to label the staining dishes with the identity and concentration of the contents. Findings: 1. Observation of the staining system showed that the containers for the stains did not have labels identifying the contents. 2. During the survey on 09/27/2023 at 12:20 PM, the HT confirmed that the containers used for staining in the histology department did not have labels identifying the contents of each solution used in the staining process.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the "Reagent Medium Receipt/QA [quality assurance] Log" and interview with the histology technician (HT), the laboratory failed to ensure that the lot numbers and expiration dates of the stains used were not used past the recorded expiration date. Findings: 1. The "Reagent Medium Receipt/QA Log" records for 2022 and 2023 were reviewed to ensure documentation of the lot numbers (#) and expiration dates of the stains and solutions used during the staining process. 2. The records show that the lot #H057-21 for Eosin was opened on 12/15/22 and expired on 03/06/23. The next entry for Eosin, lot #M14-13 was opened on 06/12/23 and expired on 06/21/24. There is a gap 88 days between when lot #H057-21 expired and when lot #M14-13 was opened. 3. During the survey on 09/27/23 at 12:20 PM, the HT confirmed that the records failed to include all of the lot # and expiration dates of the Eosin stains that were used in the laboratory.
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 quality assurance (QA) records, and interview with the histology technician (HT) and laboratory director (LD), the LD failed to document review of the "Quarterly Quality Assurance Checklist" each quarter. Findings: 1. The "Quarterly Quality Assurance Checklist" worksheets for 2022 and 2023 were reviewed. 2. Each checklist was dated and included checkmarks next to each item on the list. The checklist failed to include the initials of who performed the review. The HT stated that the LD performed the review each quarter. 3. During the survey on 09 /27/2023 at 12:20 PM, the HT and LD confirmed that the "Quarterly Quality Assurance Checklist" failed to include the initials of the LD after the review was performed.