

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0990495	(X3) Date Survey Completed 08/29/2025
Name of Provider or Supplier Skin Care Physicians Llc D/B/A Boynton Beach Skin	Street Address, City, State 7740 Boynton Beach Blvd, Boynton Beach, FL	
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 CLIA recertification survey was conducted at Skin Care Physicians LLC dba Boynton Beach Skin on August 14, 2025 to August 29/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6168 493.1487 Condition: Testing Personnel
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for three of 48 days when Mohs procedures were performed in 2023. Findings: 1. Review of the Modified Routine Hematoxylin & Eosin Stain log revealed the control slide stain acceptability was not approved by the Doctor on 07/26 /2023, 12/20/2023, and 12/27/2023, 2. Review of the Mohs Accession Log showed there were 16 Mohs procedures on 07/26/2023, 10 Mohs procedures on 12/20/2023, and 8 Mohs procedures on 12/27/2023, 3. During an interview on 08/14/2025 at 12:45 PM, the Histology Technician acknowledged that H&E stain quality was not documented.</p>
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control</p>

procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to have a log documenting the preparation of the reagents used for Hematoxylin and Eosin (H&E) stain and used in the tissue processor from 04/05/2025 to 08/14/2025. Findings: 1. A tour of the laboratory on 08/19/2025 at 9:35, revealed the flammable cabinet contained only 100% Reagent Alcohol. 2. Review of the Quality Control Worksheet Modified Routine Hematoxylin and Eosin Individual Chemical Analysis showed the laboratory used 95% Alcohol dilution during the staining process. 3. Review of the list of chemicals used in the Tissue Tek Vacuum Infiltration Processor (VIP) showed the VIP used 70% Alcohol and 95% Alcohol were used during the processing of the tissue. 4. Review of quality control logs showed there was no log that showed the date the dilutions were made, the lot number and expiration of the 100% alcohol used to make the dilution, and the date of expiration for the dilution. 5. During an interview on 08/14/2025 at 1:10 PM, the Histology Technician stated they did not have a preparation log for the alcohol dilutions.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the Dermatopathology reports, and interview, the laboratory failed to report where the professional component was performed for five of five (#1, #2, #3, #4, #5) Patient Dermatopathology reports reviewed. Finding: 1. Review of the Dermatopathology reports revealed the reports failed to include the name and address of where the professional component was performed. 2. During an interview on 08/14/2025 at 1:55 PM, the Histology Technician acknowledged the Dermatopathology Report did not list where the biopsy slides were read.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and 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 record review and interview, the Laboratory Director failed to ensure quality control and quality assessment programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they

occurred from 04/05/2023 to 08/14/2025 Finding: Review of the procedure titled, Quality Assurance read, "A checklist is used monthly. The items on the checklist are used to monitor and maintain compliance with the various portions of the Quality Assurance Program." Review of the procedure titled Job Description for Laboratories performing Tests of High Complexity Laboratory Director noted, "Ensure the quality controls and quality assurance programs are established and maintained to assure quality of the laboratory services provided and to identify failures in quality as they occur." Review of the logs titled Quality Control Worksheet Modified Routine Hematoxylin and Eosin Individual Chemical Analysis, Microscope Verification and Maintenance Log, Quality Control Worksheet for the Cryostat Temperature, Room Temperature / Humidity, and Safety Equipment Monitoring Record failed to indicate if logs were reviewed by the Laboratory Director. Review of the quality control and quality assurance documents revealed there was no checklists available to review. During an interview on 08/14/2025 at 2:59 PM, the Histology Technician stated there were no checklists filled out for the Mohs laboratory. During an interview on 08/14/2025 at 3:00 PM, the Histology Technician stated the Laboratory Director did not sign off on the quality control logs.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to ensure that one (C) of three Testing Personnel (A - C) performing high complexity tests in Histology had appropriate proof of education. (See D6171)

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each

specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure that one (C) of three Testing Personnel (A - C) performing high complexity tests in Histology had appropriate proof of education. Findings: 1. Review of Centers for Medicare and Medicaid Services Form 209, Laboratory Personnel (CLIA), signed by the Laboratory Director on 08/11/2025 listed three Testing Personnel (A, B, C). Testing Personnel C performed the technical testing component of grossing on patient samples for Histology testing. 2. Review of Testing Personnel C's personnel records showed the Laboratory Director signed the Grosser Evaluations performed on 02/07/2023 and 02/05/2024, and the Annual Grossing Competency Review performed on 01/29/2025 3. Review of Testing Personnel C's personnel records showed her transcript failed to include proof of 24 semester hours of science courses that included 6 semester hours of chemistry; 6 semester hours of biology; and 12 semester hours of chemistry, biology, or medical laboratory technology in any combination to qualify for High Complexity Testing Personnel performing patient grossing. 4. During an interview on 08/14/2025 at 10:10 AM, the Histology Technician stated there was no other college transcripts for Testing Personnel C.