

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2110285	(X3) Date Survey Completed 03/24/2026
Name of Provider or Supplier Suncoast Skin Solutions Inc	Street Address, City, State 500 Vonderburg Dr Ste 302e, Brandon, 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 Suncoast Skin Solutions, Inc. on 03/24/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6168 493.1487 Condition: Testing Personnel.
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory employed one (I) of five Testing Person(s) (F - J) performing grossing (macroscopic tissue examination) who did not meet the High Complexity Testing Personnel qualifications for the subspecialty of Histopathology. See D6171.</p>
D6171	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(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)</p>

(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, one (I) of five (F - J) Testing Personnel (TP) who performed grossing (macroscopic examination of tissue) failed to meet the educational requirements for the subspecialty of Histopathology. Findings included: 1. The CMS-209 Laboratory Personnel Report form, signed and dated by the Laboratory Director on 03/24/2026, was reviewed. TP F - J were listed as performing high complexity testing. 2. "Competency Assessment For Grossing Personal" forms were reviewed. TP I's date of hire was documented as 04/17/2023. 3. TP I's highest level of education was a Bachelor of Science degree in Health Sciences degree. Their transcript was reviewed. It failed to meet the minimum requirements as specified at (b)(3)(ii)(A)(2). 4. An interview was conducted with the Laboratory Director on 03/24/2026 at 4:50 p.m. They were not aware TP I failed to meet the minimum requirements specified at (b)(3)(ii)(A)(2).