

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2106853	(X3) Date Survey Completed 10/27/2025
Name of Provider or Supplier Coastal Dermatology Laboratory	Street Address, City, State 4400 Hwy 20e Ste 410, Niceville, 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 Coastal Dermatology Laboratory on 10/22/2025-10/27/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6063 493.1201 Condition: Laboratory 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 with both Testing Personnel (TP #A and TP #B) the laboratory failed to verify the education and licensure of 1 (TP #A) out of 2 Testing Personnel prior to performing Patient testing (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) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a</p>

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 one Testing Personnel (#A) of two Testing Personnel (#A, #B) did not meet the qualifications for performing testing in the subspecialty of Histopathology from 08/15/2025-10/22/2025. Findings included: 1. The Form CMS-209 Laboratory Personnel Report (CLIA), signed by the Laboratory Director on 10/08/2025 was reviewed. Testing personnel (TP) #A was documented as high complexity testing personnel. 2. Documentation of education was reviewed. TP #A had an AS in General Education. TP #A's unofficial transcripts were reviewed. The transcripts documented an AS in General Education, with a major in Emergency Medical Technician program. Documentation stated TP #A has 8 hours of biology and 8 hours of chemistry, missing 12 hours of additional classes in either chemistry, biology, or medical laboratory technology. 3. An initial grossing competency evaluation for TP #A, signed by the Laboratory Director 08/15/2025, showed TP #A was evaluated for grossing of patient tissue. 4. An interview with TP #A and TP #B on 10/22/2025 at 11:15 a.m. confirmed TP #A performed grossing of Patient specimens (high complexity testing). 5. Review of the Form CMS-116 (Application for Certification for a survey) signed by the Laboratory Director on 10/08/2025 documented an annual test volume of 7605 patient tests for the subspecialty of Histopathology. A printed log of grossed specimens revealed TP #A grossed a total of 103 specimens between 8/15/25 and 10/22/2025.