

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0990498	(X3) Date Survey Completed 08/14/2025
Name of Provider or Supplier Boca Raton Dermatology Pa	Street Address, City, State 5258 Linton Blvd Ste 306, Delray 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 Boca Raton Dermatology PA from 8/12/25 to 8/14/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6168 493.1487 Condition: Laboratory Testing Personnel
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure one of one newly hired Testing Personnel who performed Histology testing, had received the appropriate training and demonstrated competency prior to testing to perform all testing operations reliably to provide and report accurate results from 1/15/2025 to 8/12/2025, (Testing Personnel C), Findings included: 1. Job Description for Laboratories performing tests of High Complexity for Laboratory Director read at item #11-Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. 2. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 8/6/2025 listed one new testing personnel, Testing Personnel C since the last recertification survey on 4/7/2023. Testing Personnel B stated on 8/12/25 at 12:10 PM that Testing Personnel C started testing at the laboratory performing grossing of biopsy patient samples on 1/15/25. 3. Documentation of training and demonstration of performing all testing operations reliably prior to testing patients' specimens was not provided at the time of</p>

the survey for Testing Personnel C. Three month review of Testing Personnel C dated 4/15/25 was provided for grosser evaluation. 4. On 8/12/25 at 12:10 PM, the Laboratory Director confirmed there was no documentation of training and demonstration of performing all testing operations reliably prior to testing patient specimens for Testing Personnel C.

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 one Testing Personnel (C) of three Testing Personnel (A, B, and 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 Testing Personnel (C) of three Testing Personnel (A, B, and C) performing high complexity tests in Histology had appropriate proof of education. Findings included: 1-Review of Centers for Medicare and Medicaid Services FORM 209, Laboratory Personnel (CLIA), signed by the Laboratory Director on 8/6/25 listed three Testing Personnel (A, B, C). Testing Personnel B and C performed the technical testing component of grossing on patient samples for Histology testing. 2- On 8/12/25 at 12:10 PM, Testing Personnel B explained Testing Personnel C started testing at the laboratory performing grossing of biopsy patient samples on 1/15/25. 3-Review of Testing Personnel C's personnel records and 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-On 8/12/25 at 12:20 PM, the Laboratory Director stated they thought Testing Personnel C qualified.