

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2301108	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Live Oak Dermatology Pc	Street Address, City, State 7176 West Ridge Road, Fairview, PA	
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 initial survey was conducted by the Pennsylvania State Agency at Live Oak Dermatology PC on 03/04/2025. The laboratory was found out of compliance with the following condition: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to ensure that the verification of accuracy for macroscopic histopathology examinations were performed at least twice annually, as required for 1 of 1 tests not included in subpart I from 03/21/2024 to the date of the survey. Findings include: 1. On the day of the survey, 03/04/2025 at 9:00 am the laboratory failed to provide documentation for the verification of accuracy for macroscopic (grossing) histopathology examinations performed at least twice annually from 03/21/2024 to 03/04/2025. 2. The LD confirmed the finding above on 03/04/2025 at 9:00 am.</p>
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>

This CONDITION is not met as evidenced by:
Based on review of personnel qualification records, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to ensure that 1 of 2 Testing Personnel (TP) met the requirements to perform high complexity testing from 03/21/2024 to the date of the survey. Refer to 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) 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 lack of documentation, review of the CLIA laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the Histology Technician, (HT) and the laboratory failed to ensure that of 1 of 2 testing personnel (TP) met the requirements to perform high complexity macroscopic histopathology examinations from 3/21/2024 to date of survey were qualified. Findings include: 1. On the day of survey, 03/04/2025 at 9:00 am, the laboratory failed to provide personnel qualification records for 1 of 2 TP (CMS 209 TP #2) who performed high complexity macroscopic histology examinations from 3/21/2024 to

the day of survey. 2. The LD and HT confirmed the finding above on 03/04/2025 at 9:00 am.