

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0412127	(X3) Date Survey Completed 12/05/2025
Name of Provider or Supplier Deerfield Dermatology Ass Ltd	Street Address, City, State 707 Lake Cook Rd Ste 280, Deerfield, IL	
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	A recertification survey was conducted on 12-05-25. The laboratory was found to be out of compliance with the CLIA regulations (42 CFR Part 493) for the following condition-level deficiencies: 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity; testing personnel.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel) Form, laboratory policies and procedures, lack of documentation, and interview with the laboratory representative, the laboratory failed follow written policies and procedures to assess the competencies of one of three testing personnel (TP) performing high complexity tissue grossing in the subspecialty of histopathology in 2024 and 2025. Findings include: 1. Review of the CMS-209 (Laboratory Personnel) Form identified three TP (TP: 1, 2 and 3) performing high complexity tissue grossing in 2024 and 2025. 2. Review of the laboratory policies and procedures identified the procedure titled "Technical consultant job description/responsibilities" which stated, "(9) evaluating and documenting the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation". 3. Review of laboratory personnel records showed the laboratory failed to have competency assessments completed semiannually for one of three TP for tissue grossing in the subspecialty of histopathology. 4. Interviews</p>

with the laboratory representative on 12/05/2025, at 09:09 am, confirmed that the laboratory failed to complete competency assessments for high complexity tissue grossing TP as required.

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 review of laboratory personnel records, lack of documentation, and interview with laboratory representative; the laboratory failed to ensure one of nine testing personnel met the educational requirements for high complexity testing. 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 review of laboratory personnel records, lack of documentation, and interview with the laboratory representative; the laboratory failed to ensure one of nine testing personnel (TP) met the educational requirements for high complexity testing. Findings include: 1. Review of personnel educational documentation revealed one of nine TP, TP #3, failed to have qualifying documentation for high complexity testing prior to reporting test results starting in 2025. 2. Interview with laboratory representative on 12/5/2025, at 2:57 pm, confirmed no educational documentation was available to qualify TP #3 as a high complexity testing personnel.