

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2141488	<b>(X3) Date Survey Completed</b>  07/31/2025
<b>Name of Provider or Supplier</b>  Elite Dermatology Pllc	<b>Street Address, City, State</b>  27131 Fulshear Bend Dr, Fulshear, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertified onsite survey was completed on 07/31/2025. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D6143</b>	<p><b>GENERAL SUPERVISOR QUALIFICATIONS</b> CFR(s): 493.1461</p> <p>(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited</p>

institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's CMS 209, random review of patient final reports from July 2025, and confirmed in an interview, the laboratory failed to document the TS review within 24 hours for all physical examinations/description, including color, weight, measurement and other characteristics of the tissues; or other mechanical procedures for 4 of 4 patient reports reviewed. The findings were: 1. Review of the laboratory's submitted CMS 209 Laboratory Personnel Report, signed by the laboratory director (LD) on 07/31/2025, revealed the laboratory identified 1 TS and 1 TP performing high complexity testing (grossing). 2. Further review of CMS 209 Laboratory Personnel Report, signed by the laboratory director on 07/31/2023, revealed the TP is not qualified as a TS. 3. Random review of patient final reports from July 2025 revealed no documentation of the TS review within 24 hours for all physical examinations/description, including color, weight, measurement and other characteristics of the tissues; or other mechanical procedures for 4 of 4 patient reports reviewed. Accession#: EDL25-003809 Date Collected: 07/10/2025 Date Received: 07/11/2025 Date Reported: 07/22/2025 Accession#: EDL25-004330 Date Collected: 07/25/2025 Date Received: 07/28/2025 Date Reported: 07/29/2025 Accession#: EDL25-004335 Date Collected: 07/25/2025 Date Received: 07/28/2025 Date Reported: 07/29/2025 Accession#: EDL25-004337 Date Collected: 07/25/2025 Date Received: 07/28/2025 Date Reported: 07/29/2025 4. An interviewed on 07/31/2025 at 2:30 pm in the MOHS lab, the practice manager confirmed the above findings. Key: TS=Technical supervisor TP=Testing personnel CMS=Center of Medicare and Medicaid Services