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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>05D2312806       | <b>(X3) Date Survey Completed</b><br>01/26/2026 |
| <b>Name of Provider or Supplier</b><br>Stein Dermatology, A Professional Corporation                                       | <b>Street Address, City, State</b><br>1101 E Pennsylvania Ave, Escondido, CA |   |
| 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>   |
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| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>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:<br/>Based on interview with Laboratory Director (LD), four (4) random patient sampling, and review of laboratory's Proficiency Testing (PT) records on January 26, 2025, it was determined that the Laboratory failed to ensure that the accuracy of the Histopathology test was verified at least twice annually for the years 2025. The findings include: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery, which is not listed in the subpart I of the 42 CFR part 493. The laboratory started testing patient samples in October 2025. For the test procedure not listed in subpart I the laboratory must verify the accuracy of the test procedure twice annually. 2. On January 26, 2025, at approximately 1:00 p.m., the LD affirmed that the laboratory did not verify the accuracy of Histopathology test in 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on September 02, 2025, stated that the laboratory performs 400 histopathology tests annually.</p> |
| <b>D5407</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's policies and procedures manuals and an interview with the Laboratory Director (LD) on January 26, 2026, it was determined that the</p>   |

laboratory director failed to approve and sign the procedure before laboratory began using it. The findings included: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery. The laboratory started testing patient samples in October 2025. 2. On January 26, 2026, at approximately 1:00 p.m. the office manager confirmed that the laboratory director did not approve, sign and date the step-by-step testing procedure before laboratory use it. 3. The laboratory's testing declaration form, signed by the laboratory director on September 02, 2025, stated that the laboratory performs 400 histopathology tests annually.