| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>05D2032820 | **(X3) Date Survey Completed**<br><br>04/09/2025 |
|---|---|---|
| **Name of Provider or Supplier**<br><br>Santa Barbara Skin Institute | **Street Address, City, State**<br><br>2921 De La Vina St, Santa Barbara, CA | |

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 |
|---|---|
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's observation during the laboratory tour, review of the laboratory's policy and procedure, and interviews with practice manager (PM) and medical assistant (MA), the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the survey on April 9, 2025, at approximately 3:30 p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 2. The PM and MA confirmed by interviews April 9, 2025, at approximately 3:40p.m., that the laboratory lacked a written safety procedures based on the laboratory's risk assessment. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 4/8/2025, the laboratory processed and reported approximately 1,200 Dermatopathology patients' test samples. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on the lack of a Quality Assurance plan (QA), review of the laboratory's policies and procedures, and interview with the office practice manager (PM), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings include: 1. Based on the day survey on April 9, 2025, at approximately 3:00 p.m., no documentation could be retrieved by the laboratory to show that a QA plan was in place for the years 2024 and 2025. 2. The PM confirmed by interview on April 9, 2025, at approximately 3:00 p.m., that the laboratory did not establish a QA plan to follow written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration submitted on April 9, 2025, signed and dated by the laboratory director on April 8, 2025, the laboratory performed annually 1,200 Dermatopathology analysis and diagnosis without an established QA plan. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual and interview with the practice manager (PM) the laboratory failed to perform quality assessment that included a review of the effectiveness of corrective actions taken to resolve problems, and/or revision of policies and procedures necessary to prevent recurrence of problems and failed to document all general laboratory systems quality assessment activities. The findings included: 1. The laboratory lacked a quality assurance policy manual to follow and document quality control for all phases of testing (preanalytic, analytic, and postanalytic), and incidents and actions taken that affected the quality of the patient testing. 2. The laboratory did not have any records of quality assessment or an incident log or other means of documentation of incidents. 3. The PM affirmed this deficiency by interview on April 9, 2025, at approximately 3:15 p.m. 4. The laboratory records performing approximately 1,200 patient specimens annually. |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interviews with the laboratory's practice manager and medical assistant on April 9, 2025; the laboratory director is cited herein due to failure to ensure that several |

| | |
|---|---|
| | aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include D3011, D 5291 and D5293. |