

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0565938	<b>(X3) Date Survey Completed</b> 04/10/2025
<b>Name of Provider or Supplier</b> South Bay Skin & Cancer Medical Group, Inc	<b>Street Address, City, State</b> 256 Landis Ave Ste 300, Chula Vista, 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>
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory staining apparatus for Mohs slides and three 1-Gallon containers of Ethanol labeled "Reagent Alcohol 100%", and interview with a laboratory administrative person, it was determined that the laboratory failed to establish Safety procedures to store the Reagent Alcohol in a Flammable Safety Cabinet to ensure protection from fire hazards. Findings included: 1. The laboratory had a staining rack for Mohs slides that included Alcohol. 2. The laboratory stored three 1-Gallon containers of 100% Reagent Alcohol/Ethanol (Medical Chemical Corporation) in an overhead wooden cupboard. 3. The office manager affirmed (4/10/25 at 12:00 PM) the aforementioned findings. 4. Thus, the laboratory failed to establish Safety procedures to store the containers of Reagent Alcohol/Ethanol in a Flammable Safety Cabinet. 5. The safety of laboratory personnel was not assured. .</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 review of laboratory records, the lack of records for 2022, 2023, and 2024; and interview with laboratory personnel, it was determined the laboratory failed to at</p>

least twice each calendar year verify the accuracy of each Testing Person to perform Mohs procedures and report pathology for Frozen Biopsy specimen. Findings included: 1. Laboratory Personnel Report (CMS209, 3/07/25) included three Testing Persons. The CLIA Application (CMS116, 3/07/25) documented testing in Histopathology: Mohs procedures and Biopy pathology. 2. Mohs procedures a. Laboratory records selected for this survey review documented Mohs procedures performed in 2022, 2023, and 2024, as follows: Date Mohs ID Testing Person (Mohs Surgeon) ----- 1/24/22 M22-28 Testing Person- 1 11/28/22 M22-293 Testing Person- 2 6/05/23 M23-150A Testing Person- 2 11/20/23 M23-345 Testing Person- 1 12/18/23 M23-372 Testing Person- 3 4/08/24 M24-102 Testing Person- 2 8/19/24 M24-230A Testing Person- 3 " M24-230B Testing Person- 3 10/14/24 M24-273 Testing Person- 1 b. Records documented the frequency of peer review of Mohs cases performed by each Testing Person, as follows: 2022 2023 2024 ----- Testing person-1 0 0 0 Testing person-2 0 0 0 Testing person-3 na 1 1 c. The Laboratory administrative person affirmed (4/10/25 at 2:00PM) the aforementioned findings; and thus, the laboratory failed to at least twice annually verify the accuracy of Mohs procedures performed by each Testing Person /Mohs surgeon. d. The quality and accuracy of the Mohs procedures performed by each Testing Person to clear tumors was not assured for this CLIA survey. 3. Frozen Biopsy Specimen a. Laboratory records selected for review during this survey documented Frozen Biopsy performed during Mohs procedures, as follows: Date FBX ID Testing Person ----- 11/28/22 M22-293 Testing Person-2 6/05/23 M23-151A Testing Person-2 " M23-151B Testing Person-2 10/14/24 M24-273 Testing person-1 b. The laboratory was unable to provide for review records verifying the accuracy of pathology reported for Frozen Biopsy specimen. c. The Laboratory administrative person affirmed (4/10/25 at 2:00PM) the aforementioned findings; and thus, the laboratory failed to have a written policy and practice to verify the accuracy of each Testing Person reporting pathology for Frozen Biopsy specimen. d. The reliability of each Testing Person to report Frozen Biopsy pathology accurately was not assured for this CLIA survey. 4. The laboratory performed 388 Histopathology tests annually, including Mohs procedures and Frozen Biopsy. .

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with laboratory personnel, it was determined that pathology reports failed to include the name of the person rendering the pathology. Findings included: 1. Laboratory reports titled "Microscopic Surgical Pathology Report" were randomly selected for review, as follows: Date collected Skin biopsy ----- 2/03/22 Nasal dorsum 5/25/22 Left dorsal index finger metacarpophalangeal joint 2. The reports failed to include the

name of the Testing Person reporting the pathology. 3. The Laboratory administrative person affirmed (4/10/25 at 2:15 PM) the aforementioned findings. 4. The reliability and quality of the pathology reports was not assured for this CLIA survey. .

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of laboratory reports and interview with laboratory personnel, it was determined that the reports failed to include the date of the report. Findings included:  
1. Laboratory reports titled, "Microscopic Surgical Pathology Report", were randomly selected for review, as follows: Date collected Skin biopsy  
----- 2/03/22 Nasal dorsum 5/25/22 Left dorsal index finger metacarpophalangeal joint  
2. The pathology reports failed to include the date reported. 3. The Laboratory administrative person affirmed (4/10/25 at 2:15 PM) the aforementioned omissions of report dates. 4. The reliability and quality of the lab reports was not assured during this CLIA survey. .