| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D1012717 | 05/12/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Skin Physicians & Surgeons Medical Group Inc | 859 E Foothill, Blvd Ste B, Upland, 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 |
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| **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 observations during the laboratory tour, review of the policy and procedures, and interviews with the team lead (TL); it was determined that the laboratory failed to have and follow written safety procedures for the laboratory to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to provide at the time of the survey May 12, 2026, safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed based on a laboratory's risk assessment. 2. The TL affirmed by interviews on May 12, 2026, at approximately 12: 30 p.m., that the laboratory did not have a written and approved safety plan for the laboratory. 4. The safety of laboratory personnel cannot be assured at this time. 5. The annual testing declaration form submitted at the time of the survey stated 3,200 samples were processed and reported for Dermatopathology laboratory tests, including the time when the laboratory failed to follow safety procedures. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. |

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| | This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of ten (10) patients' Mohs procedure testing records including log-in documents, Mohs notes, mapping, final reports, slides, and an interview with the office manager (OM) and team lead (TL); the laboratory failed to follow established policies and procedures to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. The findings include: 1. The surveyor reviewed ten (10) patient records for the Mohs procedure and Histopathology reports. For three (3) out of ten (10) patient reports reviewed discrepancies were found as follows: a. For a patient Mohs performed on 09/16/2025 the slides show a state II, mapping also indicated Sate II. However, notes only describe Stage I in the final report. b. Two (2) patients samples processed for Mohs on two different dates 7/25/ 2025 and 10/31/2025, slides reviewed indicate Toluidine Blue stain was used for the diagnosis. The Mohs notes description of the stages of Basal Cell Carcinoma describe Hematoxylin and Eosin (H&E) stain as used for the diagnosis. No H&E-stained slides were found. 3. The OM and TL affirmed by interviews on May 12, 2026, at approximately 12:45 p.m. that records were discrepant as described in 1.a. and b. and were missed from performing corrective action reports. 4. The laboratory's testing volume declaration submitted at the time of survey stated that 2,850 Histopathology Mohs tests were performed and reported annually including the time when the discrepancies occurred. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of Proficiency Testing (PT) records (peer review) for Parasitology, the surveyor's review of ten (10) randomly selected patient test reports, and interviews with laboratory's team lead (TL); the laboratory failed to document the parasitology tests performed, patients' results, peer review, and quality control for the years 2025 and 2026. The findings included: 1. The laboratory conducted Parasitology microscopic testing for the years 2025 and currently (2026). For test procedures not listed in subpart I, the laboratory must verify the accuracy of the test procedure twice annually, document date of test performed, results observed and perform quality control procedures each time the test is performed. 2. The laboratory had no records to show peer review for parasitology testing was performed at least twice annually. 3. No documentation was found for the parasitology tests performed since the lab started testing in 2025. No log-in sheet was available with the patients' pertinent information and microscopic results reported in the patients' clinical charts. 4. On May 12, 2026, at approximately 11:30 a.m., the TL confirmed that the laboratory did not maintain a record for twice annual peer review or documentation of the tests performed for 2025 and 2026. 4. The laboratory's testing declaration form, signed by the laboratory director on May 12, 2026, stated that the laboratory performed approximately 50 parasitology tests annually. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a) |

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| | (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's policies and procedures, ten (10) randomly selected patient test results, and interviews with the laboratory's team leader (TL), the laboratory failed to have written procedures manuals for all tests, assays, and examinations performed by the laboratory available and followed by laboratory personnel. The findings included: 1. The laboratory lacked written and LD approved policies and procedure for all tests, assays and examinations currently performed in the laboratory. 2. The laboratory written procedures for the following test were missing or incomplete; Mycology (KOH) and Parasitology (scabies) microscopic examinations. 4. Reliability of the laboratory tests' performance based on complete laboratory procedures to follow by testing personnel to ensure compliance with federal CLIA regulations could not be assured during this survey. 5. The TL affirmed by an interview on May 12, 2026, at approximately 12:00 p.m. that the laboratory failed to provide LD signed, dated, and approved laboratory procedures for all the current tests and examinations performed in the laboratory. 6. According to the testing declaration form (CMS-116) submitted at the time of survey, the laboratory processed, tested, and reported approximately a total of 350 patient tests annually for KOH and scabies (Sarcoptes scabiei) when the laboratory lacked written and approved policies and procedures manuals. |
| **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 proficiency testing (peer review) documentation, randomly selected patient test records, and interviews with the laboratory's office manager and team lead; the laboratory director is herein cited due to failure to ensure that several aspects of the test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;. The findings include: D 3011, D5203 and D5217. |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor's review of laboratory's policy and procedure, personnel competency evaluation documents, and interview office manager and team lead; the laboratory director failed to ensure that the laboratory established policies and procedures for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings include See D5401. |