| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2115541 | 05/14/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Precision Dermatology Inc | 770 Tamalpias Dr Ste 403, Corte Madera, 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 laboaratory tour, and interviews with the office manager (OM) and medical assistant (MA); it was determined that the laboratory failed to follow safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to follow their safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed based on the laboratory's risk assessment. 2. Surveyor's observation during the laboratory tour noted that no eye wash station nor portable bottle was found. 3. The OM and MA affirmed by interviews on May 14, 2025, at approximately 10:50 a..m., that the laboratory lacked an eye wash station or portable bottle as mentioned in statement #2. 4. The safety of laboratory personnel and patients could not be assured at this time. 5. The annual testing declaration form submitted at the time of survey stated 350 samples were processed and reported for Dermatopathology during the time when safety concern for all personnel and patients could not be assured. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policy and procedure, peer review records, seven (7) randomly selected patient records, and interviews with the office manager (OM) and medical assistant (MA); it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the years 2022, 2023, and 2024. The findings include: 1. The laboratory's policy and procedure for proficiency testing stated that two cases are sent to another facility to verify the accuracy of results for Dermatopathology. However, only one case per year was available for review for the years 2022, 2023, and 2024. Therefore, the accuracy of patient results could not be assured. 2. This deficient practice is a repeat of non-compliance as affirmed by interviews with the OM and MA on May 14, 2025, at approximately 9:38 a.m., and that the laboratory failed to follow protocol as mentioned in statement #1. 3. The laboratory's testing declaration form submitted at the time of the survey stated that 350 tests Dermatopathology were processed and reported annually during the time that laboratory failed to perform verification of at least two cases annually as required. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policy/procedure, quality assessment documentation, Mohs preventive maintenance (PM) log, seven (7) patient testing records, and interviews with the office manager (OM) and medical assistant (MA); the laboratory is herein cited for failure to retain the differential stain quality control (QC) slide for 2021. The findings include: 1. The laboratory worked with an external Mohs company to process patient samples and slides. For each patient day of testing, a differential stain QC slide was made. 2. The QC slide on August 21, 2021 could not be located affecting one out of 7 patient records reviewed. This was also missed when quality assessment was performed quarterly by the laboratory. 3. This deficient practice was affirmed by interviews with the OM and MA on May 14, 2025, at approximately 10:40 a.m. as mentioned in statement #2. 4. According to the laboratory testing volume submitted at the time of survey, 350 Dermatopathology tests were processed and reported during the time the QC slide for differential staining could not be located. |
| **D6084** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(2)<br><br>provide a safe environment in which employees are protected from physical, chemical, and biological hazards;<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policies and procedures, observations during the tour of the facility, and interviews with the office manager |

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| | and medical assistant on May 14, 2025, the laboratory director is herein cited due to failure to provide a safe environment in which both employees and patients are protected from physical, chemical, and biological hazards. See D3011. |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policies and procedures, proficiency testing records, seven patient test records and interviews with the office manager and medical assistant on May 14, 2025, at approximately 9:38 a.m.; the laboratory director is herein cited for failure to perform verification of test accuracy at least twice annually for the years 2022, 2023, and 2024. See D5217. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<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, and interviews with the office manager and medical assistant on May 14, 2025, the laboratory director is herein cited due to failure to ensure that quality control and quality assessment programs established were followed to assure the quality of services offered and identify problems as it occur. See D5601 |