

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0984472	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier Pacific Skin Institute	Street Address, City, State 1495 River Park Dr Ste 200, Sacramento, 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	<p>FACILITIES 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 the surveyor's review of the laboratory's policy and procedure, direct observations during the tour and interviews with the administrator and histology technician (HT), it was determined that the laboratory failed to follow safety policy to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The surveyor's direct observations during the laboratory tour are as follows: a. The laboratory had two eye wash stations but no documentation was available nor provided to support it was checked. b. The lack of a spill kit near the testing area. c. The four fire extinguishers found were last inspected on 8/11/2023, with no subsequent inspections noted. 2. The administrator and HT affirmed in an interview on November 4, 2025, at approximately 4:00 p.m. that the laboratory failed to perform, document, and verify the findings mentioned in statement #1. 3. The safety of laboratory personnel and patients cannot be assured at this time. 4. The annual testing declaration form (Lab-144) submitted at the time of the survey stated 1,600 Histopathology samples were processed and reported, including the time when the laboratory failed to follow safety policy.</p>
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p>

	<p>This STANDARD is not met as evidenced by: Based on the lack of policy and procedure for retention requirements and interviews with administrator and histology technician (HT) on November 4, 2025, it was determined that the laboratory failed to establish a policy for retention requirements applicable to Histopathology as required in CFR 493.1105(a). The findings include: 1. The laboratory lacked a retention policy and procedure for all types of records applicable to Histopathology as required in CFR 493.1105(a). 2. The administrator and HT affirmed in an interview on November 4, 2025, at approximately 2:55 p.m. that the laboratory lacked the retention policy and procedure to store all types of records and slides as required. 3. According to the laboratory testing declaration form (Lab-144) signed and dated by the laboratory director on 10/15/2025, the laboratory processed and reported approximately 1,600 Histopathology samples annually.</p>
<p>D6084</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>provide a safe environment in which employees are protected from physical, chemical, and biological hazards;</p> <p>This STANDARD is not met as evidenced by: Based on the direct observations during the laboratory tour and interviews with the administrator and histology technician on November 4, 2025, the laboratory director is herein cited for failure to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. See D3011</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a retention policy and procedure, survey findings and interviews with the administrator and histology technician on November 4, 2025, the laboratory director is herein cited for failure to ensure that an approved, signed, and dated, procedure manual that accurately reflected current laboratory practices was available for all personnel. See D3013.</p>