

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2280913	(X3) Date Survey Completed 05/19/2026
Name of Provider or Supplier Newport Beach Dermatology And Plastic	Street Address, City, State 27512 Calle Arroyo, San Juan Capistrano, 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
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 a review of the laboratory's stained slides, including a random selection of one hundred and sixty (160) stained slides from 04/18/2023 to 05/19/2026, and an interview with laboratory testing personnel on May 19, 2026, it was found that 15 out of 160 slides were stuck to adjacent slides. This indicates that the laboratory failed to maintain or store stained slides according to the required conditions for proper preservation. The findings included: 1. The laboratory performed Mohs Micrographic Surgery onsite and stored the stained slides in the plastic container. 2. During the survey, a surveyor examined 160 slides collected over 11 days and discovered that 15 of them were stuck to adjacent slides Patient #1 (04/09/2024): 2 slides adhered together. Patient #2 (05/07/2024): 2 slides adhered together. Patient #3 (05/07/2024): 6 slides adhered together. Patient #4 (02/18/2025): 2 slides adhered together. Patient #5 (02/18/2025): 3 slides adhered together. 3. On May 12, 2026, at approximately 2:00 p.m., the testing personnel (TP # 2) confirmed that the above slides had adhered to each other. 4. The laboratory's testing declaration form, signed by the laboratory director on May 6, 2026, stated that the laboratory performed approximately 500 histopathology tests annually.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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>

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of Proficiency Testing (PT) records, random selection of nine (9) patient reports, and interviews with laboratory testing personnel on May 19, 2026, it was determined that two of two testing personnel did not verify the accuracy of Histopathology tests at least twice annually for the years 2023, 2024, and 2025. The findings included: 1. The laboratory conducted Histopathology testing, including Mohs Micrographic Surgery, which is not listed in subpart I of the 42 CFR part 493. For test procedures not listed in subpart I, the laboratory must verify the accuracy of the test procedure twice annually. To fulfill this requirement, the laboratory procedure manual specified that peer review must be conducted twice annually, with three Mohs cases randomly selected for each review to verify the accuracy. 2. The laboratory records show that one peer review event for four cases conducted in 2023, 2024, and 2025 by each of the two testing personnel. 3. On May 12, 2026, at approximately 1:00 p.m., the testing personnel (TP#1) confirmed that the laboratory did not maintain a record for twice annually peer review for three slides per event in 2023, 2024 and 2025. 4. The laboratory's testing declaration form, signed by the laboratory director on May 6, 2026, stated that the laboratory performed approximately 500 histopathology tests annually.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1239(a)

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.

This STANDARD is not met as evidenced by:
 Based on review of policy and procedure manuals, laboratory records, and interviews with the laboratory testing personnel on May 12, 2026, it was determined that the laboratory failed to follow its established QA/QC patient test management policy during the years 2023, 2024, 2025 and 2026. The findings included: 1. The laboratory established a policy for the QA/QC patient test management system. This policy required medical staff to review 11 specific documents every quarter to ensure appropriate quality assurance measures were maintained. 2. On May 12, 2026, at approximately 2:20 pm, the laboratory failed to provide the required quarterly reviews of QA/QC documentation to the surveyor for the years 2023, 2024, 2025, and 2026. Laboratory testing personnel (TP #2) confirmed that these documents were not maintained by the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on May 6, 2026, stated that the laboratory performed approximately 500 histopathology tests annually.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(5)

(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;

This STANDARD is not met as evidenced by:

Based on review of policy and procedure manuals, laboratory records, and interviews on May 12, 2026, at approximately 2:20 pm, it was determined that the laboratory director failed to ensure that quality assessment programs were followed to maintain the quality of laboratory services and to identify any failures in quality as they occurred during 2023, 2024, 2025, and 2026. The findings included: The laboratory director failed to ensure the established policy for QA/QC patient test management was followed in 2023, 2024, 2025, and 2026. See D5291