

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1103389	(X3) Date Survey Completed 06/12/2024
Name of Provider or Supplier Newport Beach Surgical And Medical Group, Inc	Street Address, City, State 180 Newport Center Dr Ste 158, Newport Beach, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures for biopsies and interview with the licensed vocational nurse (LVN); it was determined that the laboratory failed to have an available written policies and procedures for pathology slides from biopsies. The findings included: 1. On the day of the survey on June 12, 2024, at approximately 12:15 p.m., the laboratory failed to provide written policies and procedures for biopsies processing and testing. 2. For five (5) out of five (5) randomly selected patient test results for pathology slides performed in the lab, no policies and procedures was available at the time of survey. 3. The LVN confirmed on June 12, 2024 at approximately 12:15 p.m. that the laboratory did not have written policies and procedures available for performance of pathology slides testing. 4. Based on the annual testing declaration submitted on June 12, 2024, the laboratory performed of 451 pathology slides from biopsies.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on interview with the licensed vocational nurse (LVN) on June 12, 2024, at approximately 12:15 p.m., the laboratory director failed to ensure that an updated, approved, signed, and dated procedure manual reflecting the current practice is available to all personnel responsible for any aspect of the testing process. Findings include: See D5401.