

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0577863	(X3) Date Survey Completed 01/14/2025
Name of Provider or Supplier Robert B Carlin Md	Street Address, City, State 24953 Paseo De Valencia Ste 21b, Laguna Hills, 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 interview with Laboratory staff and review of laboratory documents on January 14, 2025, it was determined that the Laboratory failed to maintain policy and procedure manuals for histopathology testing. The findings include: 1. It was the practice of the laboratory to perform Histopathology and tissue grossing on site. 2. On the day of Survey, the laboratory failed to provide policy and procedure manuals for dermatopathology procedures performed by the laboratory. 3. The laboratory staff confirmed on January 14, 2025, at approximately 11:30 am, that the laboratory was not able to retrieve the policy and procedure manuals for the dermatopathology testing. 4. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 294 histopathology testing annually.</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: Based on interview with Laboratory staff and review of laboratory documents on</p>

January 14, 2025, it was determined that the Laboratory Director failed to ensure that approved procedure manual is available for histopathology testing. See D5104