Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1009634	02/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Gary C Lee Phd Md Inc	4980 Barranca Pkwy Ste 202, Irvine, 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
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) (c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on review of specimen grossing records, an interview with the Laboratory Director (LD), and review of five (5) randomly selected patient test results on February 17, 2026, it was determined that the laboratory failed to ensure that the reference laboratory for specimen grossing maintains a current CLIA certificate. The findings included: 1. It was the practice of the laboratory to perform dermatopathology testing. 2. On February 17, 2026, at approximately 11:30 a.m., the laboratory director confirmed that specimen grossing is referred to Harris Histology Service. 3. Harris Histology Service does not hold a current CLIA certificate and is not qualified to perform specimen grossing. 4. The laboratory's testing declaration form, signed by the laboratory director on January 21, 2026, stated that the laboratory performed approximately 1,300 histopathology tests including dermatopathology annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals and an interview with the Laboratory Director (LD) on February 17, 2026, the laboratory Director

	failed to ensure that there were approved procedure manuals available for the testing processes that are performed on site or for those which are sent to a referral laboratory. The findings included: 1. It was the practice of the laboratory to perform histopathology testing including Mohs Micrographic Surgery and mycology testing. 2. On February 17, 2026, at approximately 12:30 p.m., the laboratory failed to provide policies or procedures manuals regarding preanalytic, analytic or postanalytic testing for Mohs, Dermatopathology and KOH prep procedures that are performed on site. 3. The laboratory retained only the policies and procedures provided by Mobile Mohs for Mohs slide procedures. 4. On the day of the survey, and subsequently via email on February 18, 2026, at 4:18 pm, the laboratory director confirmed that he was unable to locate the policies and procedures manuals. 5. The laboratory's testing declaration form, signed by the laboratory director on January 21, 2026, stated that the laboratory performed approximately 1,315 tests annually.