Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2182444	04/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Golden Coast Dermatology, Skin Cancer	26732 Crown Valley Pkwy Ste 571, Mission Viejo, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals, personnel competency assessment records, review of eight (8) randomly selected patient test results and interview with the Histology Technician (HT) on April 10, 2025, the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency. The findings include: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery. The Histology Technician (HT) was responsible for performing grossing and preparing slides for histological analysis. 2. The laboratory's HT affirmed on April 10, 2025, at approximately 1:30 pm, that the laboratory did not have written policies and procedures for assessment of employee competency and maintained no documentation for competency assessment for 1 of 1 HT. 3. The laboratory's testing declaration form, signed by the laboratory director on April 8, 2025, stated that the laboratory performed approximately 200 histopathology tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Laboratory Director (LD) on April 10, 2025, it was determined that the current laboratory director failed to meet the standard requirement to approve, sign, and date all policies and procedures. The findings include: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery. 2. On April 10, 2025, at approximately 2:00 pm, the LD affirmed that the laboratory maintained no documentation indicating that written policies and procedures had been approved, signed, and dated by the current laboratory director. 3. The laboratory's testing declaration form, signed by the laboratory director on April 8, 2025, stated that the laboratory performed approximately 200 histopathology tests annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on interview with Laboratory Director (LD), review of Eight (8) random patient sampling, review of laboratory's policies and procedures manuals and personnel competency assessment records on April 10, 2025, it was determined that the Laboratory failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings include See D5209 and D5407.