Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0687205	(X3) Date Survey Completed 03/21/2025
Name of Provider or Supplier Margaret Shannon Md, Inc	**Street Address, City, State** 400 Newport Center Dr Ste 501, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on interview with Laboratory Director (LD), Ten (10) random patient sampling, and review of laboratory's Proficiency Testing (PT) records on March 21, 2025, it was determined that the Laboratory failed to ensure that the accuracy of the Histopathology test was verified at least twice annually for the years 2022, 2023 and 2024. The findings include: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery and dermatopathology testing, which are not listed in the subpart I of the 42 CFR part 493. For the test procedure not listed in subpart I the laboratory must verify the accuracy of the test procedure twice annually. 2. On March 21, 2025, at approximately 1:00 pm, the LD affirmed that the laboratory maintained no documentation to show it verified the accuracy of Histopathology test at least twice annually for 3 of 3 years. 3. The laboratory's testing declaration form, signed by the laboratory director on March 20, 2025, stated that the laboratory had performed 2350 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 laboratory's policies and procedures manuals, proficiency testing records, review of Ten (10) randomly selected patient test results and interview with Laboratory Director (LD) on March 21, 2025, it was determined that the Laboratory director of high complexity testing failed to ensure that the quality assessment programs maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: According to the laboratory's written procedures for Mohs Micrographic Surgery verification of test accuracy, the laboratory selects minimum of one Mohs case at least twice annually for peer review by a board-certified dermatologist. On March 21, 2025, at approximately 1:00 pm, the LD affirmed that the laboratory maintained no documentation to show it verified the accuracy of Histopathology test at least twice annually for 3 of 3 years. See D5217