Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0870989	08/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kathleen Hutton Md, Inc	1441 Avocado Ave, Ste 309, 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 the surveyor's review of Proficiency Testing (PT) records and an interview with the laboratory staff on August 5, 2025, it was determined that the Laboratory did not verify the accuracy of the Histopathology tests at least twice annually for the years 2023, 2024 and 2025. The findings included: 1. It was the practice of the laboratory to perform Histopathology testing including Mohs Micrographic Surgery, which is not listed in subpart I of the 42 CFR part 493. For test procedures not listed in subpart I, the laboratory must verify the accuracy of the test procedure twice annually. 2. On 08 /05/2025 at approximately 11:00 am, the laboratory staff confirmed that the laboratory did not verify the accuracy of the Histopathology testing twice annually for 2023, 2024 and 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on July 18, 2025, stated that the laboratory performed approximately 1200 histopathology tests annually. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory documents and an interview with the laboratory staff on August 5, 2025, at 11:15 a.m., it was determined that the laboratory failed to maintain policy and procedure manuals for histopathology testing. The findings included: 1. It was the practice of the laboratory to perform Histopathology testing including Mohs Micrographic Surgery. 2. On the day of the Survey, the laboratory failed to provide policy and procedure manuals for histopathology procedures performed by the laboratory and the laboratory staff confirmed their inability to retrieve manuals. 3. The laboratory's testing declaration form, signed by the laboratory director on July 18, 2025, stated that the laboratory performed approximately 1200 histopathology tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of five (5) randomly selected patient test results and interview with the laboratory staff on August 5, 2025, it was determined that the laboratory failed to indicate the test report date accurately and consistently with the test performed. The findings included: 1. A review of the labratory patient test records for Mohs Micrographic Surgery showed that 1 of 5 patients had inconsistent and incorrect dates throughout the slide preparation, Mohs mapping, and final report. The following test dates were inconsistent: Final report date: 1/9/2023 Mohs mapping date: 1/1/2024 Slide preparation date: 1/9/2024 2. On 08/05/2025 at approximately 11:30 am, the laboratory staff affirmed that the tests reported had inconsistent dates for slide preparation, Mohs mapping, and the final report for the selected patient #3. 3. The laboratory's testing declaration form, signed by the laboratory director on July 18, 2025, stated that the laboratory performed approximately 1200 histopathology tests annually.