Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0576370	08/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kim Tang Md Inc	23832 Rockfield Blvd, Ste 210, Lake Forest, 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 review of laboratory testing records, the lack of records, and interview with laboratory administrative personnel, it was determined the laboratory failed to verify the accuracies of pathology reported for Biopsies and Mohs procedures to clear tumors in 2023. Findings included: a. The Biopsy Log Books recorded procedures performed during the timeframe 2022 - 2024. Cases randomly selected for review for this survey included the following: Report Date Slide ID Testing person ---------- 1/11/23 KT23-39A Dr C 1/26/23 KT23-131A Dr C 1. The laboratory failed to have any records documenting Peer Review of Biopsy slides reported by Dr. "C" in 2023. b. The Mohs Log Books recorded procedures performed during the timeframe 2022 - 2024. Cases randomly selected for review for this survey included the following: Date ID Testing person ---------- 1/20/23 A, S Dr KT 1. The laboratory failed to have records documenting at least twice Peer Review of Mohs procedures performed by Dr. "KT" in 2023. c. Laboratory administrative personnel affirmed (8/15/24 at 1:00 PM) the aforementioned findings; and thus the laboratory's failure to verify the accuracy of Biopsy pathology reports and Mohs procedures for all testing persons. d. The quality and reliability of testing in 2023 could not be assured. Laboratory administrative personnel affirmed (8/15/24 at 2:50 PM) the total annual volume of Biopsies and Mohs procedures performed in 2023, as follows: Testing person Test volumes, 2023 ---------- Dr "C" 168 Biopsies Dr "KT" 606 Mohs procedures .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory records, the lack of records, and interview with the laboratory administrative person, it was determined the laboratory had failed to establish a written policy and procedure for an ongoing process to regularly monitor the peer review process, assess for completion, and correct problems as they occur. Findings included: a. The laboratory failed to identify in 2023 that peer reviews were not completed for all testing persons reporting Biopsy pathology reports and performing Mohs procedures. b. The laboratory administrative person affirmed (8/15 /24) there was no practice or written quality assessment policy and process for monitoring the records of peer review to identify problems as they occurred. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the deficiencies cited, it was determined the Laboratory Director was deficient in providing overall administration to ensure that a written policy and practice was established and maintained to monitor and assess the quality of the peer review process. Findings included: a. Peer review was incomplete for 2023 and the laboratory had no process to identify this. The Laboratory Director was unaware of the problem in 2023.