| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D0576370 | 08/28/2019 |
| **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 |
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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of lack of laboratory documents, and interview with the laboratory personnel, it was determined that the laboratory failed to ensure, at least twice annually, the accuracy of the PPM and general histopathology testing which are not included the subpart I of CFR part 493 and failed to document all proficiency testing evaluations and verification activities in CFR 493.1236 (d)). The findings included: a. The laboratory performed Provider Performed Microscope (PPM), a moderate complexity testing, and general Histopathology, a high complexity testing, which are not included in subpart I of CFR part 493. b. In order to ensure the accuracy of the testing systems, the laboratory may: 1) enroll in a proficiency testing (PT) programs, 2) blind testing of material with known results, 3) other external assessment programs (provided in a professional workshop), 4) peer review with a CLIA qualified peer, or etc. c. The laboratory failed to document all proficiency testing evaluation and verification activities required in CFR 493.1236 (d), D-5221, and failed to ensure the accuracy, at least twice annually, of the testing for PPM and general Histopathology CFR493.1236 (c)(1). |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 through 493.1236. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of lack of laboratory's peer review documents, and interview with the laboratory personnel and the laboratory director, it was determined that the laboratory failed to follow its written policies and procedures (P&P) for an ongoing mechanism to monitor, assess, the proficiency of testing performance, and failed to document its monthly quality assurance (QA) by peer review for evaluation of proficiency testing performance of the general pathology. The laboratory failed to establish its P&P for an ongoing mechanism to monitor, assess and document the PPM testing system at least twice annually to ensure the accuracy of the PPM testing proerfomance. The findings included: a. The laboratory performed general pathology (GP), Mohs surgery, and PPM by KOH/Wet mount procedures. b. In order to ensure the accuracy, reliability of the GP testing performance, the laboratory established its written P&P to evaluate the proficiency testing performance at least twice annually for accuracy verification (CFR 493.1236 (c) (1)). c. The laboratory's QA P&P state that "General Path: All Drs reviewed by Dr. Bell except Dr. Tang review Dr. Bell. Routine is minimum one biopsy per doctor monthly". d. At the time of survey (08/30/2019 @ 11:45 AM), the laboratory director affirmed that the doctors exchanged second opinions for their general GP cases when they met in the clinic hallway, but failed to document the review activities between peers what they had agreed upon or followed its written QA P&P in item (c) mentioned above. e. The laboratory failed to follow written P&P, and failed to document all QA activities, and failed to ensure the evaluation of proficiency testing performance for GP monthly as stated in itswritten QA procedures. f. The laboratory also performed KOH/Wet mount for the examination of presence or absence of fungi or scabies in their medical practice. g. The laboratory failed to establish its P&P for an ongoing mechanism to monitor, assess its KOH/Wet mount testing performance, and failed to document all activities. h. See D-5217 for failure to ensure and document the accuracy of the PPM testing system. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review on lack of laboratory's procedure manual (PM), and interview with the laboratory personnel, it was determined that the laboratory failed to establish a written PM for Provider Performed Microscopy (PPM) using potassium hydroxide (KOH)/Wet mount to examine for presence or absence of fungi or parasites from skin samples, and failed to make PM available to, and followed by, laboratory personnel. The findings included: a. The laboratory performed KOH/Wet mount to examine skin samples for presence or absence of fungi or parasites. b. FDA (Food and Drug Administration) categorizes KOH/Wet mount as moderate complexity testing. c. There were no written PPM procedures pertaining to KOH/Wet mount examinations available, and followed by laboratory personnel at the time of survey (8/28/2019 @ 11:15 am). d. The current laboratory director must approve, sign, and date the procedures 493.1251 (d). |

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| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's testing procedure manual (PM) and laboratory operation activity documents, and interview with the laboratory director and the laboratory personnel, it was determined that the laboratory director failed to be responsible for the overall operation including but not limited to assurance of compliance with the applicable CLIA regulations, proficiency of testing performance, and ensuring the establishment and maintenance of acceptable levels of analytical performance for KOH/Wet mount and general histopathology testings. The findings included: a. The laboratory failed to establish written PM and QA programs for KOH /Wet mount testing, a moderate complexity testing, to examine the presence or absence of fungi or parasite (see D-5401) b. The laboratory failed, at least twice annually, to ensure and document the accuracy of the KOH/Wet mount testing activities, a moderate complexity testing (see D-5217) c. The laboratory performed general pathology/histopathology, which is not included in the subpart I of CFR part 493, and failed to follow its written QA procedures, and failed to document the peer review activities to ensure and evaluate the accuracy of general pathology performances, a high complexity testing, at least twice annually (see D-5217 and D-5291) |