

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0580125	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier James T Wang Md Inc Hb	Street Address, City, State 17822 Beach Blvd, Ste 468, Huntington 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patients' test records, the lack of laboratory documents, and interview with the Laboratory Director (Technical Supervisor/Testing Person), it was determined that the laboratory failed to verify the accuracy of histopathology testing, including biopsies and Mohs procedures, at least twice annually in 2017 - 2018. Findings included: a. The laboratory stated (Laboratory Testing Declaration, 10/21/19) approximately 400 histopathology tests were performed annually. Reports reviewed from 2017 -2018 included 9 biopsy pathology reports and 5 Mohs procedures. b. The laboratory failed to provide documents verifying the accuracy of biopsy pathologies and Mohs procedures final stage of clearing tumor in 2017 - 2018. c. The Laboratory Director (Technical Supervisor/Testing Person) affirmed (10/24/19 at 12:00pm) the failure to have a written policy and practice of at least twice annually verifying the accuracy of biopsies and Mohs procedures testing. .</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the lack of an approved procedure manual and interview with the Laboratory Director, the laboratory failed to have written procedures for laboratory personnel to follow for preanalytic, analytic, and postanalytic activities. Findings included: a. The laboratory failed to provide for review written procedures approved by the Laboratory Director for activities such as positive identification of patients, the management of biopsy and Mohs specimen, record keeping, quality assessment, quality assurance, retention times, and other pertinent processes. b. The Laboratory Director (Technical Supervisor/ Testing Person) affirmed (10/24/19 at 12:00pm) the laboratory's failure to have an approved manual of written procedures for personnel to follow. .

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on interview and the lack of approved written procedures and laboratory documents, the Laboratory Director is herein cited for deficient practice in ensuring a quality control program was established and maintained to assure the quality of pathology reports and Mohs procedures and identify failures as they occur. Findings included: a. The Laboratory Director affirmed (10/24/19 at 12:00pm) the failure to establish and maintain a program of activities to ensure quality and accuracy. b. See D5217. .

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on interview and the failure to have a laboratory manual, the Laboratory Director is herein cited for deficient practice in providing a manual of approved written policies and procedures for preanalytic, analytic, and postanalytic processes. Findings included: a. The Laboratory Director affirmed (10/24/19 at 12:00 pm) the failure to have a written manual of approved policies and procedures since 2017.