

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0995348	<b>(X3) Date Survey Completed</b> 07/13/2022
<b>Name of Provider or Supplier</b> Vincent C Hung Md	<b>Street Address, City, State</b> 351 Hospital Rd Ste 418, Newport Beach, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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 the laboratory's quality assurance (QA) policies and procedures (P&amp;P), peer review of the Mohs map records, interview with the laboratory staff, it was determined that the laboratory failed to perform evaluation of proficiency testing performance (Eval) at least twice annually to ensure accuracy, reliability and timely of the patient test result reports. The findings included. a. The laboratory performed evaluation of proficiency testing performance (Eval) twice annually in April and October (the laboratory staff verbally affirmed). b. Two cases of Mohs slides were sent to outside a qualified testing personnel on 4/20/21 and were received and returned with "Yes" agree for the final diagnoses of the slides on 6/29/2021. c. There were no other send out for peer review in 2021. d. The laboratory staff affirmed that the cases to be send out were in Dr.'s office not yet sent. e. The laboratory performed histopathology in approximately 85 patient samples monthly. f. The laboratory failed to perform evaluation of proficiency testing performance for the testing personnel required by CLIA rules and regulation in 2021 and 2022 and failed to follow its policies and procedures. g. The laboratory staff affirmed (7/13/2022 @ 11:05 am) that the laboratory failed to perform evaluation of proficiency testing performance at least twice annually.</p>
<b>D5401</b>	<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</p>

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 review of the laboratory's "Equipment Quality Control-Cryostat" policies and procedures (P&P), "Cryostat Temperature and Maintenance Log", and interview with the laboratory staff, it was determined that the laboratory failed to follow its written policies and procedures (P&P) to perform and operate its analytical systems. The findings included as follows: a. The laboratory performs Mohs surgery and process histological preparation and staining procedures onsite. b. A Cryostat device was used to cutting the tissue and the Cryostat acceptable (optimal) temperature range was set between -20 to -30 Celsius in its written "Equipment Quality Control-Cryostat" c. The day use of Cryostat temperature recording on the chart, Cryostat Temperature and Maintenance Log" indicates the acceptable Cryostat temperature for cutting the tissues between -15 to -29 degree Celsius, which is inconsistent with its written P&P of -20 to -30 degree Celsius. d. Review of "Cryostat Temperature and Maintenance Log" between 3/24/22 thru 7/12/22, there noted that 13 out of total of 28 recorded below -19 degree Celsius which were out of its written acceptable temperature range of -20 to -30 degree Celsius. Date Temp Date Temp (Date in 2022; Temp = temperature in Celsius) 3/31 -19 4/5 -17 4/12 -19 4/14 -19 4/19 -19 4/21 -18 4/26 -18 4/28 -18 5/3 -19 5/12 -19 5/19 -19 6/16 -19 7/12 -15 e. The laboratory failed to take remedial actions and investigate the Cryostat temperature conditions out of acceptable temperature range toward its histology process each day when used.

**D5407**

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's "QUALITY ASSURANCE MANUAL" for VINCENT C. HUNG, MD NEWPORT OFFICE, and interview with the laboratory staff, it was determined that the laboratory failed to provide evidence to show the current laboratory director had approved, signed, and date the procedures and changes in procedures of "QUALITY ASSURANCE MANUAL". The findings included: a. Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. b. The current laboratory director failed to approve, sign and date the current procedure manual, "QUALITY ASSURANCE MANUAL".

**D5791**

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's written policies and procedures (P&P) and laboratory temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to follow its written P&P for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. The laboratory performed Mohs surgery and histopathology onsite for skin tissues diagnoses. b. The laboratory had established written P&P for its evaluation of proficiency testing performance for the qualified testing personnel. c. The laboratory failed to follow its written P&P, see D-5217. d. The laboratory had established written P&P for Cryostat's acceptable temperature range for its cutting skin tissue. e. The laboratory failed to follow its written P&P, see D-5401 f. The current laboratory director failed to approve, sign and date the laboratory procedures., see D-5407

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 the laboratory's written policies and procedures (P&P) and laboratory temperature records, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory performed Mohs surgery and histopathology onsite for skin tissues diagnoses. b. The laboratory director failed to follow its Quality Assessment /Assurance to assess Evaluation of Proficiency Testing Performance for histopathology and failed to ensure the accuracy, reliability and timely of the patient test result reports. See D-5217 d. The laboratory director failed to follow Quality Assessment/Assurance to monitor Cryostat's acceptable temperature range records and take remedial actions as they are out of the range. See D-5401