

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0995348	<b>(X3) Date Survey Completed</b>  09/25/2020
<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 the surveyor's review of the laboratory's records for evaluation of proficiency testing performance and an interview with laboratory personnel (LP) on 9/25/2020 between 10:30 a.m. and 12:00 p.m., it was determined that the laboratory failed to at least twice annually, document their quality assurance/proficiency testing for the year 2018. Findings include: 1. On 9/25/2020, an inspection was conducted between 10:30 a.m. and 12:00 p.m. 2. During a review of the laboratory documentation, it was noted at approximately 11:00 that the laboratory failed to document peer proficiency testing for MOHS Histopathology in 2018. The LP recognized that this documentation was missing. 3. MD peer review documentation was present for 2019.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's testing reagent expiration dates, and an interview with laboratory personnel (LP) on 9/25/2020 between 10:30 a.m. and 12:00 p.m., it was determined several reagents used for tissue staining were expired.</p>

Findings include: 1. On 9/25/2020, an inspection was conducted between 10:30 a.m. and 12:00 p.m. 2. During a review of the reagent expiration dates , it was noted at approximately 11:15, that several reagents had expired dates.. The LP recognized that several of these reagents were expired. These reagents are currently in use. 3. The vendor, reagent, lot # and expiration dates are indicated below Vendor Reagent Lot# Expiration Date MCC Bluing Sol. 8449 00 6/3/2020 MCC Harris H&E 8670 00 2/28 /2020 MCC Acid Alch. 8165 01 4/30/2020

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on the surveyor's review of the laboratory's records for evaluation of testing performance and the associated stain QC, and an interview with laboratory personnel (LP) on 9/25/2020 between 10:30 am and 12:00 p.m., it was determined there was a time gap in which there was no record of daily slide stain QC. Findings include: 1. On 9/25/2020, an inspection was conducted between 10:30 am and 12:00 p.m. 2. Records were available for daily H&E daily stain QC through most of April, 2018, but there were no daily QC records for May of 2018 through July of 2020. The LP recognized this gap in the log sheets. 3. Records were available beginning in August of 2020. 4. There was limited or no testing in the March/2020-July/2020 timeframe due to reduced activity related Covid-19 associated reduction in patient activity.

**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 an audit of 5 patient reports as part of the quality assessment review (in the date range of 1/1/2018-2/4/2020) and the associated tissue slides, the laboratory failed to establish/monitor an ongoing mechanism to detect mistakes of slide labeling (analytic process). Findings include: 1. On 9/25/2020, an audit was conducted from 10:30 a.m. to 12:00 p.m. with a review of 5 randomly selected MOHS patients 2. One of the audit cases demonstrated an inconsistency in the procedure date on the slide vs. the patient report. The patient under review indicated a procedure date of 11/13/18 on the MOHS report, and the slide label indicated a date of 11/6/18. 3.A representative of the laboratory (LP) confirmed on (9/25/2020 at 10:45 a.m. that the above descriptions were inconsistent. No corrective action was documented.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's records for evaluation of patient reporting, proficiency testing, reagent expiration and daily stain QC, and an interview with laboratory personnel (LP) on 9/25/2020, it was determined that the laboratory director failed to ensure that several aspects of analytic and post analytic phases were not being monitored. 1. Activities to assess and monitor peer proficiency, stain QC, stain expiration and slide/reporting consistency were not performed at times. See D-tags 5791, 5217, 5417 and 5435.