

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2173817	(X3) Date Survey Completed 01/07/2025
Name of Provider or Supplier Chuang T Hung Md	Street Address, City, State 629 N 13th Ave, Upland, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observation, review of five patient test records, lack of maintenance documentation and equipment control policy and procedure, and interview with the histology technician (HT), it was determined that the laboratory failed to establish and follow a maintenance protocol for the E200 Nikon microscope that ensured its continued performance necessary for accurate and reliable test results. The findings include: 1. Based on the review of the laboratory's policy and procedure manual, no control page was found to indicate approval, establishment, and/or review. The surveyor also observed that the laboratory lacked an equipment quality control policy and procedure. 2. Based on the review of five patient test records on January 7, 2025, at approximately 9:30 a.m., no evidence or service report records were found to support that the microscope was maintained for calibration since year 2020. The surveyor also observed that the microscope was nowhere to be found. 3. The HT affirmed by interview on January 7, 2025, at approximately 9:30 a.m. that the laboratory failed to have an established maintenance protocol for the E200 Nikon microscope used for histopathology slide examinations as mentioned in statement #1. 4. The HT also stated in an interview during the survey that the microscope was removed from the facility prior to the survey and that service reports for the microscope found were only from 2019. 5. Based on the laboratory's annual testing</p>

declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 1,200 samples during the time the microscope was not calibrated since year 2020. Thus, the accuracy and reliability of patient reports cannot be assured.