

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0887094	(X3) Date Survey Completed 02/07/2022
Name of Provider or Supplier Richard G Bennett M D	Street Address, City, State 50 Alessandro Pl, Ste 130, Pasadena, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the testing personnel (TP); it was determined that the histopathology laboratory lacked an eye wash station near the area for processing Biopsy and Mohs samples. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey February 7, 2022, at approximately 11:30 a.m. the surveyor observed that the laboratory lacked an eye wash station closed to the area when processing and staining histopathology samples. 2. The TP affirmed the lack of an eye wash station in the histopathology laboratory. 3. Based on the laboratory's annual testing volume declaration submitted on 2/7/2022, the laboratory processes and reports approximately 326 histopathology samples.</p>
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p>

	<p>This STANDARD is not met as evidenced by: Based on the lack of an up to date policies and procedures manual, policy for documents and stained slides retention, five (5) random dermatopathology test records review, and interview with the laboratory's testing personnel (TP) on February 7, 2022, the laboratory failed to have a policy for documents and stained slides retention. The findings included: 1. On the day of survey, February 7, 2022, at approximately 12: 00 p.m. based on review of policies and procedures (P&P), the laboratory failed to provide an up-to-date P&P on the current practice including a policy for length of retention of documents, patient reports, and both biopsy and Mohs procedure-stained slides. 2. The laboratory TP confirmed by interview on February 7, 2022, at approximately 12: 15 p.m. that the laboratory did not have an updated P&P for its document and sample slide preparations retention policy. 3. The laboratory reports performing approximately 326 dermatopathology patient tests annually.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's procedure manual, lack of documentation, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to perform and document maintenance and calibration of the microscope and the cryostats as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's standard operating procedure (SOP) indicates that annual maintenance and calibration by a contracted equipment service according to manufacturer's requirements be performed on the microscope (AP microscope) and two cryostats used in the laboratory. 2. The TP confirmed on 2/7/2022 at approximately 11:30 a.m. that the laboratory failed to follow SOP for maintenance and calibration of the microscope for the years 2020 and 2021. 3. According to the annual test volume declared by the laboratory on 09/14/2021; the laboratory performs approximately 326 histopathology tests annually.</p>
<p>D6084</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.</p> <p>This STANDARD is not met as evidenced by: Based on the survey findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure a safe environment in which personnel are protected from biohazardous materials. Findings include: See D3011</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p>

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 with the laboratory staff on February 7/ 2022 at approximately 12:00 p.m., the laboratory director failed to ensure that an updated, approved, signed, and dated, procedure manual reflecting the current practice is available to all personnel responsible for any aspect of the testing process. Findings include: See D3043.