

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0584671	<b>(X3) Date Survey Completed</b> 11/09/2021
<b>Name of Provider or Supplier</b> J Robert West, Md Inc DbA Luminous Dermatology	<b>Street Address, City, State</b> 504 W Pueblo St, Ste 102, Santa Barbara, 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>D3011</b>	<p><b>FACILITIES</b> 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 the surveyor's observation, review of records, and interview with the technical consultant (TC) and testing personnel (TP); it was determined that the histopathology laboratory lacks a monitor to measure the amount of formalin (chemical) exposure the TP receives on the cumulative basis by processing biopsy samples preserved in formalin daily and did not have a fire extinguisher either available in the laboratory. The laboratory failed to observe safety procedures to ensure protection from physical and biohazardous materials. The findings included: 1. On the day of the survey November 9, 2021 at approximately 11:30 a.m. the surveyor observed that the histology TP processing samples in the laboratory lacked a formalin exposure monitor and a fire extinguisher in or near the laboratory. 2. The TC and TP affirmed the lack of a formalin (chemical) exposure monitor to process histopathology samples as well as the lack of a fire extinguisher nearby. 3. Based on the laboratory's annual testing volume declaration submitted on November 9, 2021, the laboratory processes and reports 4,236 histopathology tests.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:  
Based on the lack of documentation, review of testing personnel competency assessment records, five (5) randomly chosen patient records review, and interview with the technical consultant (TC) and testing personnel (TP) on November 9, 2021, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess histopathology processing and testing personnel competency. Findings include: 1. Based on review of the laboratory's policies and procedures, the laboratory failed to establish and follow written policies and procedures for competency assessment of the histopathology laboratory TP. 2. For (one) 1 out of (one) 1 TP from the histology laboratory, the laboratory fail to provide documentation of training or competency assessment for the TP processing biopsy samples at the laboratory for the years 2020 and 2021. 4. This deficient practice was affirmed by interview with the TC and TP on November 9, 2021 at approximately 12:00 p.m.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:  
Based on the lack of documentation of the Histotech water bath, paraffin embedding instrument, and miscellaneous equipment's temperature logs in the histopathology laboratory, review of maintenance records, and interview with the laboratory's technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the equipment used to process biopsy samples. The findings included: 1. The laboratory grosses, processes, and prepares tissue slides from biopsy samples. 2. No records of temperature daily logs of the equipment used in the histology laboratory were found for the years 2020 and 2021. 3. The laboratory's TC and TP confirmed on November 9, 2021 at approximately 12:00 p.m. that the laboratory failed to follow the manufacturer's instruction to document the temperature of water baths, paraffin embedding, and other equipment used at the time of processing biopsy samples in the histopathology laboratory

**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 review of the laboratory's records for policies and procedures, employees' competency records, lack of temperature logs documentation, and interview with the technical consultant and laboratory personnel on November 9, 2021; it was

determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D3011, D5209, and D5429.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of lack of the personnel competency evaluation records and interview with the technical consultant; it was determined the laboratory failed to produce and follow written policies and procedures to assess its employees' competencies. The findings included: See D5209.