

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2015439	<b>(X3) Date Survey Completed</b> 07/02/2024
<b>Name of Provider or Supplier</b> Exer Medical Corporation	<b>Street Address, City, State</b> 3160 E Del Mar Blvd, Ste 110, Pasadena, 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>D3003</b>	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on surveyors' observation during the laboratory tour of the molecular testing lab and interview with the laboratory's technical consultant on July 2, 2024; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen processing for SARS-CoV-2 testing (COVID-19). Findings include: 1. During the laboratory tour at approximately 12:30 p.m. the surveyors observed the area assigned for COVID-19 sample processing and testing by the Sofia analyzer took place on an open bench with no protection from aerosols. In addition, computer entry and storage for other reagents and instruments were in the same testing area. 2. During an interview on July 2, 2024, at approximately 1:00 p.m. the TC confirmed that the molecular testing for the presence of COVID-19 laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples in the same area/room. 3. The laboratory's testing declaration form, signed by the laboratory director on July 2, 2024, stated that the laboratory performs approximately 1,000 waived test which include testing for COVID-19.</p>
<b>D3011</b>	<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>

This STANDARD is not met as evidenced by:  
Based on observation and interview with testing personnel (TP) and technical consultant (TC); it was determined that the laboratory lacked a biosafety cabinet (BSC) or shield when processing respiratory samples of SARs-CoV-2 using the Sofia analyzer. During the tour of facility, surveyor also observed gloves in the regular trash can. The laboratory failed to establish and observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey July 2, 2024, at approximately 12:00 p.m. the surveyor observed that the laboratory lacked a BSC or shield in the area where respiratory samples are processed. The surveyors also observed gloves in the regular trash can. 2. The TC affirmed the lack of a BSC or shield when processing samples to be tested by the Sofia analyzer. The TP and TC affirmed the presence of gloves in the regular non-biohazard trash container in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 07/02/2024, the laboratory processes and reports 11,160 samples annually.

**D6011**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(2)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:  
Based on direct observation during the laboratory tour and interviews with technical consultant and laboratory personnel; it was determined that the laboratory director failed to provide a safe environment in which employees are protected from biological hazards and cross contamination of samples and equipment. See D3003 and D3011.