

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2015439	(X3) Date Survey Completed 09/30/2026
Name of Provider or Supplier Exer Medical Corporation	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3001	FACILITIES CFR(s): 493.1101(a)(1) (a) The laboratory must be constructed, arranged, and maintained to ensure the following: (a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on the surveyors' observation of the laboratory testing area and an interview with laboratory personnels (LPs); it was determined that the laboratory testing area failed to provide adequate space, ventilation, and utilities necessary for conducting all phases of the testing process. The findings included: 1. The laboratory area consists of approximately 12 x 3 square feet or less of counter space built into the facility's narrow hallway in which sample receiving and processing, preparation of reagents and controls, loading of testing instruments, analyzing and reporting test results for both waived and moderate complexity tests took place. The counter space for the laboratory instruments and other small equipment; a computer workstation, a sink with an eyewash station, and the actual workbench area is very limited, and all sections are next to each other. The testing area itself is crowded with a high risk for patients and employees to bump into the testing personnel or testing equipment and fails to ensure sample integrity and quality of testing. In addition, the proximity of testing areas increases the risk of sample cross contamination. 2. The LPs confirmed on September 30, 2026, at approximately 4:30 p.m. that the laboratory testing space fails to provide adequate working areas and physical barriers to protect specimens and reagents from contaminants when conducting all phases of the testing process: preanalytical, analytical and postanalytical. 3. The laboratory's testing declaration form, signed by the laboratory director on September 30, 2026, stated that the laboratory performs approximately 11,160 moderate complexity tests and 6,000 waived tests annually, and quality of testing cannot be assured at this time.

D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on the surveyors' direct observation during the lab tour, review of policies and procedures, and an interview with laboratory personnels (LPs), the laboratory failed to provide a work area that ensures that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. The findings included: 1. The surveyors observed during the laboratory tour a LP performing SARS antigen and Influenza A+B immunoassay tests who failed to use the designated splash guard /shield due to lack of sufficient space as well as crowding of the work area by facility staff and patients. In addition, the LP failed to inform the surveyors as well as individuals within the laboratory testing area that he was performing tests on respiratory specimens that can potentially aerosolize infectious pathogens. 2. The LPs confirmed during an interview at approximately 4:30 p.m. that the LP failed to follow safety protocol while performing a lab test due to the limited space available in the laboratory bench work area. 3. The laboratory's testing declaration form, signed by the laboratory director on September 30, 2026, stated that the laboratory performs approximately 11,160 moderate complexity tests and 6,000 waived tests annually, and quality of testing cannot be assured at this time.
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on the surveyors' direct observation of the laboratory operation, test performance, and interview with laboratory personnels (LPs); it was determined that the laboratory director failed to ensure that the physical plant, space, organization, and environmental conditions of the laboratory are appropriate for the testing performed. See D3001.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) 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 the surveyors' direct observation during the laboratory tour and interviews with laboratory personnels (LPs); it was determined that the laboratory director failed to provide a safe environment in which employees are protected from biological hazards. See D3003.