Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2217603	(X3) Date Survey Completed 01/06/2023
Name of Provider or Supplier Exer Medical Corporation	**Street Address, City, State** 7077 Willoughby Ave Ste 3, Los Angeles, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patient test results, and interview with the laboratory technical consultant on January 6, 2023, at 1:40 pm, the laboratory testing person failed to follow the laboratory's policy & procedure in repeating the flagged test results. The findings include: 1. The laboratory used Micros ES60 automated CBC instrument from Horiba to measure platelet (plt). The instrument print out showed an asterisk, (*) following the plt results for the sample ID 230624 out of 5 patients' samples reviewed. The instrument manufacturer's instruction stated, "An asterisk following the parameter Plt indicates that for 3 counts analyzed, all 3 counts are outside of the instrument precision limit. Results should be verified by re-running the sample". However, the laboratory person reported the results without repeating the run. Therefore, the accuracy of the reported results can not be assured and might have harmed the patient. 2. The laboratory technical consultant on January 6, 2023, at 1:40 pm, affirmed that the laboratory testing person #1 did not follow the laboratory's procedure and repeat the test. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/6/2023, stated that the laboratory performs approximately 2,000 plt tests, annually.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on January 6, 2023, at 1:40 pm, it was determined that the laboratory director failed to direct the overall operation and administration of the laboratory. The findings include: See D5401 and D6070.

D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant and testing person on January 6, 2023, at 1:40 pm, it was determined that the laboratory testing person #1 failed to follow the laboratory's procedure for repeating the sample run. The findings include: See D5401.