Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2242679	09/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Exer Medical Corporation	2613 Pacific Coast Hwy, Torrance, 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
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records, and interview with the laboratory staff on September 13, 2023, at 3:00 pm, the laboratory failed to rotate the control material testing among all operators. The findings include: 1. The laboratory performed CBC test on Micros60 automated instrument. The laboratory listed 10 operators or testing persons who performed the test. However, the laboratory document showed only one testing person (testing person #1) performed QC material test, random 10 days control run in 2023, reviewed. Therefore, the accuracy of the patient test results reported by the other operators cannot be assured and might have harmed patients. 2. The laboratory staff on September 13, 2023, at 3:00 pm, affirmed that the laboratory did not rotate QC testing among all operators. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/13/2023 stated that the laboratory performs approximately 12,000 CBC tests, annually.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records, and interview with the laboratory staff on September 13, 2023, at 3:00 pm, the laboratory failed to test control materials in the same manner as patient specimens. The findings include: 1. The laboratory performed CBC test on Micros60 automated instrument. The lab asst load the patient samples on the instrument. The laboratory operator or testing persons then reviewed and accepted the instrument's results. On the other hand, testing person #1 loaded the QC material and reviewed and accepted the instrument's results, random 10 days control and patient run in 2023, reviewed. Therefore, the laboratory did not test the control materials in the same manner as patient specimens and thus the accuracy of the patient test results reported by the laboratory cannot be assured and might have harmed patients. 2. The laboratory staff on September 13, 2023, at 3:00 pm, affirmed that the laboratory did not test control materials in the same manner as patient specimens. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/13/2023 stated that the laboratory performs approximately 12,000 CBC 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 & procedure, quality control and patient test records, and interview with the laboratory staff on September 13, 2023, at 3:00 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and thus have impaired the laboratory test quality and potentially harmed patients. The findings include: See D5463, D5465 and D6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records, and interview with the laboratory staff on September 13, 2023, at 3:00 pm, the laboratory director

	failed to ensure that the the quality control programs are established and maintained to assure the quality of laboratory services provided. The findings include: See D5463 and D5465.