Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2142899	09/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Exer Medical Corporation	3215 N Sepulveda Blvd, Manhattan Beach, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on the review of proficiency testing records and an interview with the technical consultant (September 27, 2018, 12:35 P.M.), the laboratory failed to test a proficiency sample the same number of times as a patient sample. Findings include: a. For the 2018 American Proficiency Institute (API) first testing event (Q1) event, for the Complete Blood Count (CBC) test sample 1 had a Hemoglobin of 5.8 g/dL (which the laboratory defines as a critical value). The sample was not retested. b. The technical consultant affirmed that the above proficiency sample should have been retested, but was not. c. The laboratory testing personnel reportedly will be performing approximately 75 CBC tests per month, even though the laboratory failed to retest a proficiency sample that had an analyte which had a critical value.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the review of quality control material testing and an interview with the technical consultant (September 27, 2018, 12:35 P.M.), the laboratory failed to follow the laboratory's quality control policy. Findings include: a. The laboratory has a

	quality control policy (Subject: QUALITY CONTROL AND ASSESSMENT) "Make sure all daily QC is recorded as applicable." b. On September 10, 2018 at 16:53, the Cell-Dyn 1800 recorded Seq #2609 results: WBC: 1.9; GRAN: 0.7; RBC: 2.29; HGB: 5.3; HCT: 17.9 c. The above sample lacked specimen identification. d. There was no data entry in the QC log explaning the above sample. e. The technical consultant affirmed that the testing person should have documented what caused these results (i. e., Level 1 control was run without entering the proper specimen identity).