

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2170602	(X3) Date Survey Completed 01/20/2021
Name of Provider or Supplier Exer Medical Corporation	Street Address, City, State 2090 Westwood Blvd, 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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, interview with the technical consultant (TC), and testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent which is unsatisfactory performance. The findings included: 1. On the date of the survey 01/20/2021 at approximately 11:00 a.m. based on review of the PT scores, the laboratory obtained for Hematology third proficiency event for the year 2020 (Q-3 2020) an overall score of 73% as follow: RBC Overall score 40% Sample Reported Expected Score 11 4.08 3.91 - 4.43 A 12 4.74 4.85 - 5.48 U 13 2.13 2.15 - 2.44 U 14 5.01 4.78 - 5.40 A 15 3.49 3.51 - 3.97 U A = Acceptable U = Unacceptable Hematocrit Overall score 40% Sample Reported Expected Score 11 35 32 - 38 A 12 51 41 - 48 U 13 20 16 - 19 U 14 46 42 - 49 A 15 34 28 - 33 U Platelets Overall score 60% Sample Reported Expected Score 11 227 163 - 272 A 12 179 100-168 U 13 110 53 - 904 U 14 620 452 - 754 A 15 374 255 - 726 A 2. The TC and TP affirmed on 01 /20/2021 at approximately 11:15 a.m. the laboratory obtained the PT scores in 1. 3. According to the laboratory testing declaration submitted on the day of the survey (01 /20/2020) for the years 2019-2020, the laboratory performed approximately 4,866 Hematology samples (quarterly) during the time the laboratory received an unsatisfactory PT performance score.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on the deficiency cited, the Laboratory Director is herein cited for failing in responsibility to ensure that testing personnel perform Hematology testing, including proficiency testing, as required for accurate and reliable results. See D2122.