

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2073979	(X3) Date Survey Completed 08/11/2026
Name of Provider or Supplier Exer Medical Corporation	Street Address, City, State 701 N Wendy Dr, Newbury Park, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, the American Proficiency Institute proficiency testing (PT) records, and interviews with the laboratory's technical consultants (TC) and testing personnel (TP); the laboratory failed to attain at least 80 percent acceptable responses resulting in unsatisfactory performance for Red Blood Cell (RBC) and Hematocrit (Hct) non-waived analytes for the first event of 2025 (Q1-2025). The findings included: 1. API reported an unsatisfactory proficiency testing report of 60% for the analytes RBC and Hematocrit (Non-Waived) for Q1-2025. 2. The TC and TP confirmed in an interview August 11, 2026, 1:45 p.m. that the laboratory received the unsatisfactory scores in for Q1-2025 as stated in 1. 3. According to the testing declaration form CMS 116 submitted at the time of the survey, the laboratory performed and reported approximately 2,160 patient samples annually for Hematology specialty that included RBC and Hematocrit analytes during the period when unsatisfactory scores were obtained.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

The laboratory director is herein cited for deficient practice in ensuring that systems for the analytic and postanalytic phases of the laboratory's proficiency testing were monitored and followed. See D2121.