

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2117433	(X3) Date Survey Completed 06/20/2024
Name of Provider or Supplier Exer Medical Corporation	Street Address, City, State 13303 Riverside Dr, Sherman Oaks, 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
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, five (5) randomly selected patient's samples, and interview with the testing personnel (TP); it was determined that the laboratory failed to participate on the first event of 2023 (Q1-2023) for Troponin I in Routine Chemistry. The findings included: 1. The API proficiency program gave an overall unsatisfactory score of 0% for Troponin I for Q1-2023. 2. The TP confirmed on June 20, 2024, at approximately 12:00 p.m. that the laboratory received the above proficiency score of 0% for Troponin I as described in 1. 3. The laboratory's testing declaration form, signed by the laboratory director on 06/20/24 stated that the laboratory performed 200 tests in Routine Chemistry annually.</p>
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>

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, five (5) random patients sampling, and interview with the testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Red Blood Cell (RBC) in hematology on the first event of 2023 (Q1-2023) Which was unsatisfactory performance for the testing event. The findings included: 1. The API proficiency program gave an overall unsatisfactory score of 40% for Red Blood Cell (RBC) for Q1-2023. 2. The TP confirmed on June 20, 2024, at approximately 11:30 a.m. that the laboratory received the above proficiency score of 40% for RBC as described in 1. 3. The laboratory's testing declaration form, signed by the laboratory director on 06/20/24 stated that the laboratory performed 9600 tests in hematology annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on the surveyors' observation during the laboratory tour and interviews with the laboratory's testing personnel (TP); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for small equipment used in the laboratory. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The TP confirmed on June 20, 2024, at approximately 12:15 p.m. that the laboratory failed to follow SOP for maintenance and calibration of timers for time dependent diagnostic tests used in the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on 06/20/24 stated that the laboratory performed 1,000 tests, annually.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(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:
Based on the surveyor's review of the laboratory's records, five (5) randomly selected patients tests records, and interview with the testing personnel (TP); it was determined that the laboratory director is cited herein due to failure to ensure that several aspects

of the preanalytic and analytic phases of the laboratory testing were monitored. See D2089, D2122, and D5429.