

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2138758	(X3) Date Survey Completed 09/06/2018
Name of Provider or Supplier Exer Medical Corporation	Street Address, City, State 25548 The Old Road, Ste U1, Santa Clarita, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of patient sampling test result and interview with the testing personnel and technical consultant (9/6/2018, 1600) it was determined that the laboratory failed to follow manufacturers' instructions for performing the test for Prothrombin Time (PT) using the Roche CoaguChek XS system. The findings included: 1a. The laboratory uses Roche CoaguChek XS system for analyzing PT/INR testing. CoaguChek XS PT testing manufacturer's guidelines under section: Expected results/Unusual results: "If the meter displays an error message, refer to the Error Message section of the CoaguChek XS Pro System User Manual. If the meter displays an unusual test result (other than an error message), check the following: - Certain drugs may affect results by interfering with warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result. - Changes in the patient's diet can cause unusually low or high results. - Any unusual results should always be followed up with inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error." 1b. The laboratory uses Roche CoaguChek XS system for analyzing PT/INR testing. CoaguChek XS PT testing manufacturer's guidelines under section: Expected results/Measuring range states that "Each system has a reportable range of 0.8 to 8.0 INR." b. For one (1) out of five (5) random patient sampling test results reviewed for PT/INR, covering period from 1/1/2018 to 6/15/2018. Patient #1 (PT/INR ordered 1/1/2018, 5:01P.M.), PT result was 0.0, INR was 2.0. c. The laboratory's policies and procedures manual under section "Critical Values" for</p>

Hematology states an INR ≥ 5 was considered to be a critical value. The final patient test report (EMR) flag indicated in bold letters as, "CRITICAL LOW." There were no other actions taken by the testing personnel. d. The testing personnel and the technical consultant affirmed (9/6/2018, 1600) that the laboratory analyzed and reported the PT/INR without any further actions taken. e. The laboratory's form CMS-116 submitted on 09/06/2018 estimated the waived test perform (which includes PT/INR) as 1000 tests annually, the validity of the test results reported could not be assured.

D2121

HEMATOLOGY

CFR(s): 493.851(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 review of the second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing records, laboratory's proficiency testing performance summary reports, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Red Blood Cell (RBC) count. The findings included: a. Q2-2018, API reported an unsatisfactory score of 40% for RBC count. b. For eleven (11) out of sixteen (16) random patient sampling test results reviewed covering period from 10/26/2017 to 7/7/2018, eleven (11) Complete Blood Count (CBC) which included RBC count were analyzed and reported during the time the laboratory received the unsatisfactory proficiency testing score for RBC. c. The technical consultant affirmed (9/6/2018, 1600) that the laboratory received the above unsatisfactory proficiency testing score for RBC count.

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:
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, based on the observation and review of random patient test results on 9/6/2018 (survey date) the laboratory director failed to ensure that the overall operation of the laboratory. See D 1001. (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.

D8100

INSPECTION REQUIREMENTS

CFR(s): 493.1771

Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:

Based on interviews with the technical consultant, a testing person (9/6/2018, 1600), review and observation of random patient test results covering period from 10/26/2018 to 7/7/2018, one patient had an order of PT/INR on 1/1/2018, the Prothrombin time (PT) result was 0.0 and INR result was 2.0. There was no documentation of corrective action taken by the laboratory for the zero (0) result. It was determined that the laboratory was not in compliance with specific requirements for the certificate type issued. See D1001.