

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2177140	(X3) Date Survey Completed 04/11/2022
Name of Provider or Supplier Exer Medical Corporation	Street Address, City, State 395 Silver Spur Rd, Palos Verdes Peninsula, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's procedure manual, lack of documentation, observation, and interview with the laboratory technical consultant (TC) and 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 the laboratory's digital thermometers and timers. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that annual maintenance and calibration be performed according to manufacturer's requirements on small equipment including: digital thermometers used for refrigerators, freezers, and room temperature and timers. 2. The TC and TP confirmed on April 11, 2022, at approximately 12:30 p.m. that the laboratory failed to follow SOP for maintenance and calibration of small equipment used in the laboratory which expired July 2021. 3. According to the annual test volume declared by the laboratory on 4/11/2022 the laboratory performs approximately 12,100 tests annually.</p>
D6023	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</p> <p>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)(6) Ensure the establishment and maintenance of acceptable levels</p>

of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policies & procedures, random patient testing, preventive maintenance records, direct observation, and interview with the laboratory's technical consultant on April 11, 2022; it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for small equipment used in the laboratory. See D5429.