

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1082684	<b>(X3) Date Survey Completed</b>  04/13/2022
<b>Name of Provider or Supplier</b>  Exer Medical Corporation	<b>Street Address, City, State</b>  8985 Venice Blvd Suite A3b, Los Angeles, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>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.</p> <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, seven (7) random patients sampling, and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the third event of 2020 (Q3-2020). The findings included: 1. The API proficiency program gave an overall unsatisfactory score of 60 % for Hematology for Q3-2020 which included: Sample Analyte Performance HEM-11 Hematct Unacceptable HEM-14 Hematct Unacceptable HEM-14 RBC Unacceptable 2. Based on the laboratory's annual testing declaration submitted on the day of the survey April 13, 2022; the laboratory analyzed and reported approximately 21,000 Hematology samples which included WBC, RBC, Hemoglobin, Hematocrit and platelet counts during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS confirmed on April 13, 2022, at approximately 11:45 a.m. that the laboratory received the above proficiency score of 60% for Hematology as described in 1.</p>
<b>D5429</b>	<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 supervisor (TS) 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 small equipment such as vortexes, centrifuges, and digital thermometers. 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: vortexes, centrifuges, and digital thermometers used in the laboratory. 2. The TS and TP confirmed on April 13, 2022, at approximately 12:10 p.m. that the laboratory failed to follow SOP for maintenance and calibration of small equipment used in the laboratory. 3. According to the annual test volume declared by the laboratory on 4/13 /2022 the laboratory performs approximately 94,100 tests annually.</p>
<p><b>D6095</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the laboratory's policies and procedures, lack of preventive maintenance records for all small equipment used in the laboratories, and interview with the laboratory's technical consultant and testing personnel; it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance. See D5429 and D2121.</p>
<p><b>D6148</b></p>	<p><b>GENERAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1463(a)(4)</p> <p>The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.</p> <p>This STANDARD is not met as evidenced by:  The general supervisor is cited herein for failing to monitor and verify preventive maintenance of small equipment to ensure that acceptable levels of analytical performance are maintained in the laboratory. See D5429.</p>