

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0643378	<b>(X3) Date Survey Completed</b>  05/09/2023
<b>Name of Provider or Supplier</b>  Orange County Public Health	<b>Street Address, City, State</b>  1729 W 17th St, Bldg 40, Santa Ana, 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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 standard operating procedures, lack of documentation, and interview with the laboratory director (LD), 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 digital timers used throughout the laboratory. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that annual maintenance and calibration be performed (by a contracted equipment service) according to manufacturer's requirements on small equipment. 2. The LD, TS, and TP confirmed on May 9, 2023, at approximately 3:30 p.m. that the laboratory failed to follow SOP for maintenance and manufacturer's instructions on the calibration of small equipment (timers) used in the laboratory since 2017. 3. According to the annual test volume declared by the laboratory, s director on 5/9/2023 the laboratory performs approximately 500,815 tests annually.</p>
<b>D6095</b>	<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>

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 (timers) used in the laboratory, and interview with the laboratory director, 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.