

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1066369	(X3) Date Survey Completed 04/07/2022
Name of Provider or Supplier Los Angeles County	Street Address, City, State 12750 Erickson Ave, Downey, 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, and interview with the laboratory director (LD) 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, vortexes, centrifuges, and timers. 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 including: digital thermometers used to verify automated digital temperature readings (Insensix) used for refrigerators, incubators, and freezers; vortexes, small centrifuges, and timers. 2. The LD and TP confirmed on April 7, 2022, at approximately 12:15 p.m. that the laboratory failed to follow SOP for maintenance and calibration of small equipment used in the laboratories for the year 2021. 3. According to the annual test volume declared by the laboratory on 4/7/2022 the laboratory performs approximately 457,681 tests annually.</p>
D6095	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 used in the laboratories, and interview with the laboratory director and testing personnel; it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance. See D5429.

D6148

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(a)(4)

The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

This STANDARD is not met as evidenced by:
The general supervisors are cited herein for failing to monitor and verify temperature readings and preventive maintenance of small equipment to ensure that acceptable levels of analytical performance are maintained. See D5429.