

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0670166	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Imperial County Public Health Laboratory	Street Address, City, State 935 Broadway, El Centro, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour and interview with the laboratory's director (LD); it was determined that the laboratory failed to establish safety procedures to ensure protection from biochemical and biohazardous materials. The findings include: 1. The laboratory failed to have a functional eye wash in the laboratory. 2. On the day of the survey July 24, 2024, at approximately 1:30 p.m. the surveyors observed that the laboratory lacked an eyewash in the area where samples are processed and tested. 3. The LD affirmed the lack of a functional eyewash in the laboratory's testing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 7/23/2024 the laboratory processes and reports approximately 10,600 samples annually.</p>
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 surveyor's review of the laboratory's policies and procedure, six (6) randomly chosen patient records, and interviews with laboratory director (LD), it was</p>

determined that the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for small equipment used in the laboratory for sample testing. The findings included: 1. At the time of survey on 7/24/2024, based on the surveyors' observation during the laboratory tour and review of records documentation at approximately 1:30 p.m., it was determined that the laboratory failed to perform PM and calibration on small equipment used in the laboratory for sample processing: centrifuges, rotators, and vortexes. 2. The LD affirmed on July 24, 2024, at approximately 2:00 p.m. that maintenance and calibration was missed for the equipment mentioned in #1. 3. According to the laboratory's testing declaration submitted by the laboratory the laboratory performed approximately 7,500 microbiology and 3,100 diagnostic immunology samples annually for which no preventive maintenance of small equipment was performed.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:
Based on the survey findings and deficiencies cited, the laboratory director is herein cited for deficient practice in providing overall administration of the laboratory to ensure a safe environment in which personnel are protected from biohazardous materials. Findings include: See D3011.