Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2090025	(X3) Date Survey Completed 12/11/2025
Name of Provider or Supplier Alameda County Public Health	**Street Address, City, State** 2901 Peralta Oaks Ct 2nd Fl, Oakland, 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
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor observation during the laboratory tour, review of records, and interview with the laboratory director (LD) and technical supervisors (TSs) on December 11, 2025; the laboratory failed to perform decontamination procedures for all the cabinets and areas where the reagents for the polymerase chain reaction (PCR) were prepared. Findings include: 1. During the laboratory tour at approximately 2:00 p.m. the surveyor observed that the cabinets and areas where the samples for PCR testing were processed, the preparation of the master mix for the PCR took place, and the addition of the template had no logs for documentation of decontamination procedures. 2. During an interview on December 11, 2025, at approximately 2:30 p. m., the LD and TSs confirmed that the laboratory failed to provide documentation for decontamination of all equipment and areas when processing samples for PCR. 3. The laboratory's testing declaration form, signed by the laboratory director on December 11, 2025, stated that the laboratory performs approximately 300 samples annually for PCR testing.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

	This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the laboratory's Polymerase Chain Reaction (PCR) testing for the presumptive detection of various viral agents, interviews with the laboratory's director (LD) and technical supervisors (TSs) on December 11, 2025 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have an unidirectional flow with separate areas for specimen preparation, master mix, reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the detection of various viral agents such Measles using manual methods for preparation of the Master-Mix (MM), controls and reagents, and addition of template. 2. During the laboratory tour on December 11, 2025, at approximately 3:00 p.m. the surveyor observed that preparation of reagents for the MM and sample template addition was all performed in the same room/area with no unidirectional flow. In addition, HIV and Syphilis testing were performed on the same bench next to the PCR cabinets. 3. The LD and TS confirmed by interview that the laboratory's molecular PCR testing was not set up following unidirectional flow. 4. Based on laboratory records, the laboratory performed and reported approximately 300 Real Time PCR molecular diagnostic tests annually.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor's observation and review of laboratory's workflow during the laboratory tour and interview with the laboratory's laboratory director and technical supervisors on December 11, 2025, at approximately at 3:00 p.m., the laboratory director failed to ensure that the risk of cross-contamination was minimized during the processes for the polymerase chain reaction (PCR) testing and that unidirectional flow existed when PCR testing was performed. The findings include: See D3003 and D3005.