Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643967	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Santa Clara County Public Health Department	2220 Moorpark Ave, 2nd Flr, San Jose, 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's observation during the laboratory tour, review of records, and interview with the laboratory director (LD), technical supervisor (TSs), and testing personnel (TP) June 24, 2026; the laboratory failed to minimize possible cross contamination of patient specimens, equipment, instruments, reagents, materials, and supplies during the polymerase chain reaction (PCR) procedure and overall sample processing. Findings include: 1. During the laboratory tour at approximately 2:30 p.m. the surveyor observed that over all the laboratory floor was very dirty. 2. All the biosafety cabinets (BSC) in the lab were crowded with pipettes, boxes, and some even had the BSC grill covered. 3. The surveyor observed the decontamination of the BSC where the preparation of reagents for the PCR had just taken place. The TP just passed rapidly the decontamination towelette over the working surface and did not decontaminate the equipment, pipettes used, reagents, and pipette tips boxes inside the cabinet. 4. During an interview on June 24, 2026 , at approximately 3:30 p.m., the LD, TS and TP confirmed that the laboratory failed to minimize possible cross contamination of patient specimens, equipment, instruments, reagents, materials, and supplies during the PCR procedure and non-PCR sample processing. 3. The laboratory's testing declaration form, signed by the laboratory director on June 16, 2026, stated that the laboratory performed approximately 20, 984 testing samples annually when the risk of cross contamination was not minimized.
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) preparation of the Master Mix (MM) for testing for the presumptive detection of various viral and microbiologic agents, interviews with the laboratory's director (LD), technical supervisors (TSs), and testing personnel (TP) on June 24, 2026 on its molecular amplification procedure; 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 Monkey Pox and bacterial agents using manual methods for preparation of the MM, controls, reagents, and addition of template. 2. During the laboratory tour on June 24, 2026, at approximately 3:00 p.m. the surveyor observed that preparation of reagents for the MM was performed at the entrance of the lab after receiving specimen, where staff were going back and forth passing the MM preparation PCR cabinet area. In addition, there was non-functional equipment, boxes, other TP performing tests, and paperwork surrounding the non-enclosed PCR working cabinet area. 3. The LD, TS, and TP confirmed by interview that the laboratory's molecular PCR testing was not set up in a separate area and did not follow unidirectional flow. 4. Based on laboratory test volumes reported on the Form Lab 144A , the laboratory performed and reported approximately 11,00 molecular test samples that included Real Time PCR molecular diagnostic tests annually.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the lack of a written and approved laboratory Safety Plan, the surveyor's direct observation during the laboratory tour, and interviews with the laboratory director (LD) and technical supervisors (TSs) the laboratory failed to have and follow a written safety procedures to ensure protection from physical, chemical, and biohazardous materials. The findings include: 1. The laboratory conducted and included in each test protocol a safety risk assessment when performing the tests. However, the laboratory failed to have and follow a current and approved written general laboratory Safety Plan (policies and procedures) based on a risk assessment to provide protection from physical and biohazardous materials as needed. There were no written policies and procedures for biological or chemical spills, cuts, injuries, earthquake, or fire at the time of the survey. 2. No policies and procedures were available for decontamination of surfaces and of biosafety cabinets. 3. The LD and TSs affirmed by interview on June 24, 2026, at approximately 3:00 p.m., that the laboratory lacked a current written general laboratory Safety Plan based on a risk assessment that is approved, signed, and dated by the laboratory director. 4. The

	safety of laboratory personnel cannot be assured at this time. 4. The annual testing declaration form submitted at the time of the survey stated 20,984 patient samples were processed and reported during the time when the laboratory failed to have and follow written safety procedures.
D5525	PARASITOLOGY CFR(s): 493.1264(b)(d) (b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation during the laboratory tour, lack of documentation, and interviews with the laboratory director (LD) and technical supervisor (TS); the laboratory failed to calibrate the ocular micrometer for determining the size of ova and parasites for the years 2023, 2024, 2025, and 2026. The findings include: 1. The parasitology TS could not find any documentation for the calibration of the oculars for the microscope used to read ova and parasites test samples and proficiency testing for the years 2023, 2024, 2025, and 2026. 2. The microscope had a sticker of last calibration conducted on 02/18/2021. However, no documentation of the calibration data was found. 3. The parasitology department failed to have a policy and procedure of how to conduct microscope ocular calibrations. 4. The LD and TS affirmed by interview on the day of the survey that there were no policy and procedure available for calibration of the parasitology microscope oculars and that the oculars were not calibrated for the years 2023, 2024, 2025, and 2026. 5. The laboratory's test volume declaration Form LAB 144A signed by the LD on 06/18/2026, indicated that the laboratory tested and reported 31 samples including proficiency testing samples during the time no calibration of the oculars was performed.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance/assessment plan, incident and corrective action reports, and interview with the laboratory director (LD) and technical supervisors (TSs) on June 24, 2026, the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, discussion of preanalytic, analytic and postanalytic systems quality assessment reviews with appropriate staff, and documentation of all systems quality assurance/assessment activities. Findings include: 1. The laboratory had a current policy for quality assurance and assessment; however, the laboratory failed to follow the policy for quality assessment and documentation of review of accuracy of patient reports for the years 2024, 2025, and 2026. 2. Although the laboratory had conducted patient test

	management, no documentation of self-audits for the three phases of laboratory testing (preanalytic, analytic,s and postanalytic) were documented for the years 2024, 2025, and 2026. There were no reports found at the time of the survey that included corrective actions taken to resolve the problems or revision of policy or procedures to prevent recurrence of problems. 3. The LD and TSs affirmed by interview on June 24, 2026, at approximately 1:00 p.m. that quality of testing assurance/assessment of all systems was not performed and review of the effectiveness of corrective actions was not documented for the years 2024, 2025, and 2026. 4. The laboratory reported performing approximately 20,984 laboratory tests for which quality assurance /assessment was not performed and corrective action was not documented.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's direct observation during the laboratory tour, review of policies and procedures, six (6) randomly selected patient test records, and interviews with the laboratory director, technical supervisors, and testing personnel; the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytic, analytic, and post analytic phases of the laboratory testing were monitored. The findings include D3011, D5525, and D5893.
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 June 24, 2026, at approximately at 2:30 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 as well as the non-PCR testing and that unidirectional flow existed when PCR testing was performed. The findings include: See D3003 and D3005.