Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0643989	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier San Joaquin County Public Health Lab	**Street Address, City, State** 1601 E Hazelton Ave, Stockton, 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 supervisor (TS) on June 4, 2025; the laboratory failed to perform decontamination procedures for all the cabinets and areas where the reagents for the polymerase chain reaction (PCR) are prepared. Findings include: 1. During the laboratory tour at approximately 2:30 p.m. the surveyors observed that some of the cabinets and areas where reagents for the PCR were prepared had no log for decontamination procedures. 2. During an interview on June 4, 2025, at approximately 2:30 p.m., the LD and TS 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 May 5, 2025, stated that the laboratory performs approximately 785 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 during the laboratory tour, observation of the of the laboratory's Polymerase Chain Reaction (PCR) testing for the presumptive detection of various infectious agents (Measles, Mumps, VZV, etc.), and interviews with the laboratory director (LD) and technical supervisor (TS) on June 4, 2025 on its molecular amplification procedure; the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the detection of various infectious organisms using manual and automated methods for specimen processing, extraction of DNA or RNA, preparation of the master-mix, controls, reagents, and addition of template. 2. During the laboratory tour on June 4, 2025, at approximately 2:15 p.m. the surveyors observed that preparation of the master-mix reagents, controls, and sample template addition were all performed in the same room/area. 3. The LD and TS confirmed by interview that the laboratory's molecular PCR testing was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 785 Real Time PCR molecular diagnostic tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory's tour and interview with the laboratory director (LD) and technical supervisor (TS) on the day of the survey, June 4, 2025, the laboratory failed to label various reagents and solutions used in the laboratory to indicate, as appropriate, the identity, opening, preparation, and expiration dates when such reagents and solutions are used in the laboratory. The findings include: 1. Based on the surveyors' observation during the laboratory tour on June 4, 2025, at approximately 2:30 p.m., it was noted that the laboratory lacked labeling for oxidase reagents and mineral oil solutions for identity (name, titer, strength, or concentration), received, opening, preparation, and/or expiration dates, as appropriate, used in the microbiology department. 2. The laboratory's LD and TS affirmed in an interview on June 4, 2025, at approximately 2:45 p.m., that the reagent and solution materials mentioned in statement #1 above were not labeled with the reagent name, date received, opening, preparation, and/or expiration dates, as applicable. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 12,877 bacteriology tests for which oxidase and mineral oil reagents and solutions were not labelled as regulated.
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 review of the laboratory's policy/procedure, randomly selected patient test records, preventive maintenance documentation, direct observation during the laboratory tour, and interviews with the laboratory director and technical supervisor on June 4, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytic and analytic phases of the laboratory testing were monitored. The findings include: 1. Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies used during PCR testing was not minimized. See D3003. 2. Molecular amplification procedures not contained in closed system did not have a unidirectional flow. See D3005. 3. Reagents and solutions (oxidase and mineral oil) were not labelled as regulated. See D5415.