Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643643	05/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
San Francisco Dept Of Public Health Laboratory	101 Grove St, Rm 419, San Francisco, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the WSLH laboratory proficiency testing (PT) results, Casper Report 155, Five (5) randomly selected patient records ranging from 11/15/2021 to 11/25/2023, and interviews with the laboratory's director (LD) and technical supervisor (TS); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Bacteriology which is unsatisfactory performance. The findings included: 1. The laboratory attained a score of 66% for Bacteriology laboratory developed test (LDT) on the analyte "Shiga Toxin"" obtaining Unacceptable Grades for sample SHG-6 Shiga Toxin 1 and Shiga Toxin 2 for the second PT event of 2023 (Q2-2023) 2. Based on the laboratory's annual testing declaration submitted 05/29/2024 at the time of the survey, the laboratory performed and reported approximately 117,808 bacteriology identifications on patients' samples which include LDT Shiga Toxin 1 and Shiga Toxin 2 testing. 3. The laboratory TS affirmed on 5/29/2024 at approximately 11:00 a.m. that the laboratory received the above unsatisfactory proficiency testing score.
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure 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 of the molecular testing lab and interview with the laboratory's director (LD) and technical supervisor (TS) on May 29, 2024; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen processing for the real time polymerase chain reaction (RT-PCR) testing. Findings include: 1. During the laboratory tour at approximately 3:00 p.m. the surveyor observed the area assigned for PCR sample processing, addition of template, and sample analysis for RT-PCR test took place in the same area/room. In addition, the addition of the template to the 96 well plate was performed in the same room. 2. No documentation of decontamination of sample processing, preparation of master mix, or template addition areas were found. 3. During an interview on May 29, 2024, at approximately 4:00 p.m. the LD and TS confirmed that the molecular testing laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples in the same area/room. 4. The laboratory's testing declaration form, signed by the laboratory director on May 29, 2024, stated that the laboratory performs approximately 19,303 molecular testing samples annually.
D3005	FACILITIES CFR(s): 493.1101(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 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 supervisor on May 29, 2024 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 a 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 & Mumps, Monkey Pox, and parasitic agent Plasmodium/Malaria etc., using manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on May 29, 2024, at approximately 3:30 p.m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same room/area without unidirectional flow. 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 19,305 Real Time PCR molecular diagnostic tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on the surveyor's observation of the laboratory's reagent materials used in the laboratory and interview with the laboratory's director (LD), technical supervisor (TS), and testing personnel (TP); it was determined that the laboratory failed to label various reagents to indicate the reagent's name, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on May 29, 2024 at approximately 2:45 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents used throughout the laboratory. 2. The laboratory's LD and TS affirmed in an interview conducted on May 29, 2024, at approximately 3:45 p.m. that alcohol, distilled water, and molecular testing reagents used throughout the laboratory were not labeled with the name, opening, preparation, and expiration dates or documented in a preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 172,899 test samples.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must 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 observation during the laboratory tour, review of the laboratory's records, policies and procedures, six (6) randomly selected patients' test results records, and interviews with the laboratory's director and technical supervisor on May 29, 2024; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic and postanalytic phases of the laboratory testing were monitored. See D2020, D3003, D3005, and D5415.