Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2274872	**(X3) Date Survey Completed** 11/09/2023
Name of Provider or Supplier San Diego County Public Health Modular Laboratory	**Street Address, City, State** 5587 Overland Ave, San Diego, 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**
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation of the laboratory testing area (one trailer) and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory testing area failed to provide adequate space, ventilation, and utilities necessary for conducting all phases of the clinical virology testing process. The findings included: 1. The laboratory area consist of a trailer of approximately 700 square feet or less in which specimen receiving, sample processing, preparation of reagents and controls, addition of sample template, reading, and analyzing of test results for the detection of various virus by the polymerase chain reaction (PCR) took place. In addition, the trailer is shared with Mycobacteriology sputum and other sources sample processing, and when needed the same area is also used for Bioterrorism processing and detection of select agents by PCR testing. 2. The space for the testing personnel biosafety cabinets, PCR sample processing sections, and PCR testing equipment (two (2) ABI 7500 DX instruments) is very limited, and all sections are next to each other. The testing area is crowded where TP bump into each other, it is difficult to maintain, and fail to provide sample integrity and quality of testing. In addition, the proximity of testing areas increases the risk of sample cross contamination. 3. The TS and TP affirmed on November 9, 2023, at approximately 3: 30 p.m. that the laboratory testing space, fails to provide adequate working areas, ventilation, and utilities for conducting all phases of the testing process: preanalytical, analytical and postanalytical. 4. The laboratory's testing declaration form, signed by the laboratory director on October 31, 2023, stated that the laboratory performs approximately 200 Virology PCR tests 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 technical supervisor (TS) and testing personnel (TP) on November 9, 2023 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 and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the detection of various viral agents such as Influenza A and B, Norovirus, etc. detection using manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on November 9, 2023, 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 TS and TP 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 200 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 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 November 9, 2023, at approximately 3:45 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents used throughout the laboratory. 2. The laboratory's TS and TP affirmed in an interview conducted on November 9, 2023, at approximately 3;45 p.m. that alcohol, distilled water, and molecular testing reagents used throughout the Virology 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 200 test samples.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, lack of documentation, the surveyor's observation during the laboratory tour, and interview with the laboratory director (LD), the technical supervisor (TS), and testing personnel (TP); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the PCR biosafety cabinet used for master mix and controls preparation. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The TS and TP confirmed on November 9, 2023, at approximately 3:50 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of the PCR master mix preparation biosafety cabinet. 3. According to the test volume declared by the laboratory on 10/31/2023 the laboratory performs approximately 200 virology diagnostic tests annually.
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 review of the laboratory's records for policies and procedures, patients' test results records, proficiency testing reports, direct observation by the surveyors during the lab tour, and interviews with the laboratory director, technical supervisor, and testing personnel on November 9, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the Virology laboratory testing were monitored. See D3001, D3005, D5415 and D5429.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyors' direct observations of the laboratory's Virology Modular laboratoty RNA/DNA detection testing processes and interview with the laboratory technical supervisor and testing personnel on November 9, 2023; the laboratory

	director failed to ensure that the physical plant to conduct laboratory testing using the polymerase chain reaction (PCR) is appropriate. Findings include See D3001.