

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0589686	(X3) Date Survey Completed 04/26/2022
Name of Provider or Supplier Fresno County Public Health Laboratory	Street Address, City, State 4525 E Hamilton Ave, 2nd Fl, Fresno, 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
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory director (LD), technical supervisors (TS), and testing personnel (TP) on April 26, 2022 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 presumptive detection of SARS-CoV-2 using various methods: Abbot, Perkin Elmer, and the CDC Multiplex procedures. 2. During the laboratory tour on April 26, 2022, at approximately 12:15 p.m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same open area without unidirectional flow. 3. The LD, TS, and TP confirmed by interview on 4/26/2022 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 18,113 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

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 observation of the laboratory's reagent materials used for decontamination of surface areas and other reagents used in the laboratory and interview with the laboratory director (LD) 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 April 26, 2022, at approximately 12:45 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents used throughout the laboratory (Alcohols, 1:10 Sodium hypochlorite and sterile water). 2. The laboratory's LD affirmed in an interview conducted April 26, 2022, at approximately 1:00 p.m. that the reagents mentioned in statement 1 were not labeled with the name, opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 18,113 test samples.

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 surveyor's direct observations of the laboratory's SARS-CoV-2 PCR testing processes and interview with the laboratory's director, technical supervisor, and testing personnel on April 26, 2022; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the PCR testing performed. Findings include: See D3005.