Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2166864	**(X3) Date Survey Completed** 06/20/2023
Name of Provider or Supplier Sunrise Diagnostics Laboratories Inc	**Street Address, City, State** 4111 Ocean View Blvd, Montrose, 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) 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 and interview with the laboratory director (LD) and laboratory manager (LM) on June 20, 2023; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen processing of samples for the presumptive detection of SARS-CoV-2 RNA (COVID-19) using Polymerase Chain Reaction (PCR) testing. Findings include: 1. During the laboratory tour at approximately 11:45 a.m. the surveyor observed the area assigned for sample processing, preparation of reagents and quality control, and sample analysis for the SARS-CoV-2 RNA by Direct RT-PCR test took place in the same area/room. 2. During an interview on June 20, 2023, at approximately 12:00 p.m. the LD and LM confirmed the laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples over the same area/room. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/20 /2023, stated that the laboratory performs approximately 20,000 SARS-CoV-2 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 SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory's laboratory director (LD) and laboratory manager (LM) on June 20, 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 presumptive detection of SARS-CoV-2 using manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on June 20, 2023, at approximately 11:45 a.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 LM confirmed by interview 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 20,000 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.
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 RNA detection by PCR testing processes and interview with the laboratory's, laboratory director, laboratory manager, and testing personnel on June 20, 2023; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the PCR testing performed and that contamination of samples and reagents were minimized. Findings include: see D3003 and D3005.