

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2243080	(X3) Date Survey Completed 12/04/2023
Name of Provider or Supplier Diagnostic Relief, Inc	Street Address, City, State 6857 Foothill Blvd, Tujunga, 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	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation during the laboratory tour of the lab and interview with the laboratory director (LD) on December 4, 2023; 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 for the detection of SARS-CoV-2. Findings include: 1. During the laboratory tour at approximately 12:40 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. 2. No documentation of decontamination of sample processing, preparation of master mix, or template addition areas were found. 3. During an interview on December 4, 2023, at approximately 2:30 p.m. the LD confirmed that the virology molecular testing for the detection of SARS-CoV-2 laboratory, failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples, template addition (performed in the same biosafety cabinet), and the preparation of reagents, controls, primers and probes took place in the same area/room. 4. The laboratory's testing declaration form, signed by the laboratory director on December 4, 2023, stated that the laboratory performs approximately 500 samples using RT-PCR for the detection of SARS-CoV-2 annually.</p>
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</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.

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 SARS CoV-2 (COVID19) and interviews with the laboratory's director (LD) on December 4, 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 COVID19 using manual methods for specimen processing, preparation of the master-mix, controls, reagents, and addition of template. 2. During the laboratory tour on December 4, 2023, at approximately :12:45 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 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 500 Real Time PCR molecular diagnostic tests annually

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); it was determined that the laboratory failed to perform and document maintenance and calibration/certification as defined by the manufacturer and with at least the frequency specified by the manufacturer for the PCR biosafety cabinet used for specimen processing and 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 LD confirmed on December 4, 2023, at approximately 1:00 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration/certification of the two (2) AIRCLEAN 600 PCR Stations used for PCR sample processing, reagent and master mix preparation, and addition of template. 3. According to the test volume declared by the laboratory on 12/4/2023 the laboratory performs approximately 500 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 the surveyor's review of the laboratory's records for policies and procedures, patients' test results records, preventive maintenance documentation, lack of decontamination documentation, and interviews with the laboratory's director on December 4, 2023; 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 D3003, D3005, and D5429.