

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2147767	(X3) Date Survey Completed 10/12/2023
Name of Provider or Supplier Usa Biosciences, Llc	Street Address, City, State 20695 S Western Ave, Ste 112, Torrance, 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 Polymerase Chain Reaction (PCR) testing for the presumptive detection of SARS CoV-2 (COVID19), Influenza A and B, and Respiratory Syncytial Virus (RSV) RNA and interviews with the laboratory's technical supervisor (TS) and testing personnel (TP) on October 12, 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, Influenza and RSV RNA detection using manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on October 12, 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 900 Real Time PCR molecular diagnostic tests annually</p>
D6083	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p>

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 SARS- CoV-2 (COVID19), Influenza A and B, and Respiratory Syncytial Virus (RSV) RNA detection testing processes and interview with the laboratory technical supervisor and testing personnel on October 12, 2023; the laboratory director failed to ensure that the physical plant to conduct polymerase chain reaction (PCR) testing of the laboratory is appropriate. Findings include See D3005.