Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2065162	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bioanalysis Diagnostic Laboratories	18173 S Pioneer Blvd Ste K, Artesia, 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	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 SARS CoV-2 (COVID19) and interviews with the technical supervisor (TS) on March 20, 2024 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 and automated methods for specimen processing, preparation of the master-mix, controls, reagents, and addition of template. 2. During the laboratory tour on March 20, 2024, at approximately 11:15 a.m. the surveyor observed that preparation of the master-mix reagents and sample template addition were all performed in the same room/area in an open bench. 3. The TS 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.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test

	requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on the lack of documentation, review of randomly chosen patient test results, and interviews with the technical supervisor (TS), it was determined that the laboratory failed to provide retention policy and procedure at the time of the survey. Findings included: 1. The laboratory had no available documentation to show retention policy for test requisition and authorization, test procedures, analytic systems records, proficiency testing records, and test report documents. 2. For eight (8) out of eight (8) randomly chosen patient test results reviewed covering period from 5/12/2022 to 3/13/2024 no documentation was retained or accessible for all tests performed in the laboratory for the years 2022, 2023 and 2024. 3. The TS affirmed on March 20, 2024, at approximately 11:45 a.m. that the laboratory had no documentation to show for test requisition and authorization, test procedures, analytic systems records, proficiency testing records, and test report documents. 4. The laboratory reportedly performs approximately 400 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 the surveyor's observation during the tour of the facility and interviews with the technical supervisor (TS), 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 laboratory's small equipment. The findings included: 1. The laboratory's policies and procedures indicated that annual maintenance and calibration according to manufacturer's requirements be performed on all equipment used in the laboratory (ex: vortex mixer and micro-centrifuge). 2. The TS confirmed on March 20, 2024, at approximately 12: 15 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as vortex mixer and micro-centrifuge. 3. According to the test volume declared by the laboratory on 3/20 /2024, the laboratory performs approximately 400 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 observation during the laboratory tour, review of records, and interviews with the laboratory director and technical supervisors on March 20, 2024; it was determined that the laboratory director is cited herein due to failure to ensure

	that several aspects of the preanalytic and analytic phases of the laboratory testing were monitored. See D3005, D3027, and D5429.