Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1039663	02/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lifeline Medical Laboratory Inc	10509 Burbank Blvd, N Hollywood, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing procedures and interview with the laboratory technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to be in compliance with applicable Federal, State, and local laboratory requirements and guidelines. The findings included: a. The laboratory has been certified to perform Bacteriology, Parasitology and Virology tests of the specialty of Microbiology by the State of California and Federal CLIA Regulations. b. The laboratory uses the Biofire Film Array Torch Respiratory Panel (RP) to test for the presence or absence of pathogenic organism on freshly collected swabs from clinical respiratory sites. c. The safety precautions outlined by Biofire Diagnostics, LLC protocol states: "Handle all specimens and waste materials as if they are capable of transmitting infectious agents. Observe safety guidelines such as those outlined in CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, the CLSI Document M29 Protection of Laboratory Workers from Occupational Acquired Infections or other appropriate guidelines" d. The laboratory TC and TP affirmed (02 /07/2020) that Federal, State, and local laboratory requirements and guidelines as specified by the Biofire Film Array Torch RP safety precautions were not followed as indicated in the established protocol.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous

	materials. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies & procedures and interview with the laboratory technical consultant (TC) and testing personnel (TP), the laboratory failed to establish and observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings included: a. At the time of the survey (February 7, 2020) no Personal Protective Equipment [PPE (goggles, protective face shields, biohazard container lids, etc.)] were seen during the laboratory tour and the staff could not retrieve the PPE needed to show that safety precautions were being performed for testing on the Biofire Film Array instrument. b. On February 7, 2020 at approximately 12:00 noon, the laboratory TC and TP affirmed that the laboratory did not establish and follow a safety policy procedure for using appropriate Personal Protective Equipment (PPE). c. The laboratory testing declaration form (CMS 116) signed by the laboratory director on February 7, 2020, indicates that the laboratory performs about 6,200 tests annually.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on the survey findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure a safe environment in which personnel are protected from biohazardous materials. Findings included: a. The Laboratory Director allowed the Owner to operate a laboratory without observance of a written policy to ensure that appropriate Personal Protective Equipment (PPE) is always present to protect laboratory personnel from biohazards and to establish regular monitoring to identify its adequate use when testing is performed. See D3009 and D3011.