Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2234415	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biomed Lab	4628 San Fernando Rd, Glendale, 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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records, randomly chosen patient results' review, and interview with the general supervisor (GS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Routine Chemistry analyte HDL Cholesterol. The finding included: 1. Based on review of PT records for the Q3-2022, AAB reported an unsatisfactory score report of 20% as follow: HDL Reported Expected Score Sample # # 11 69 10-19 Incorrect Result #12 44 21-39 Incorrect Result #13 60 29-53 Incorrect Result #14 92 50-93 Correct Result #15 78 4-7 Incorrect Result 2. Based on the laboratory testing declaration submitted at the time of the survey on 01/18/2023, the laboratory analyzed and reported approximately 56,000 Routine Chemistry tests including HDL Cholesterol during the time the laboratory had unsatisfactory proficiency testing results. 3. The GS affirmed on 01/18/2023 at approximately 11:45 a.m. that the laboratory received the above unsatisfactory proficiency testing scores.
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 the testing personnel (TP) on January 18, 2023, it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen receiving and processing. Findings include: 1. During the laboratory tour at approximately 1:15 p.m. the surveyor observed the area assigned for sample receiving and processing to take place over the same desk space used for demographics computer entry. 2. During an interview on January 18, 2023, at approximately 1:25 p. m. the TS confirmed the laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples over the same area where data entry took place. 3. The laboratory's testing declaration form, signed by the laboratory director on January 18, 2023, stated that the laboratory performs 122,000 samples annually.
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 observation and interview with testing personnel (TP); it was determined that the laboratory lacked a biosafety cabinet (BSC) to process respiratory samples for testing using the Biofire instrument. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey January 18, 2023, at approximately 1:00 p.m. the surveyor observed that the laboratory lacked a BSC in the area where respiratory samples are processed. 2. The TP affirmed the lack of a BSC to process samples to be tested by the Biofire instrument in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 1/18/2023, the laboratory processes and reports approximately 10,000 respiratory samples annually.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policies and procedures (P&P), test requisition, five (5) randomly chosen patients records from 5/22/2022 to 11/30/2022, and interview with the laboratory's general supervisor (GS) and testing personnel (TP); the laboratory's test requisition failed to include time of sample collection. The findings include: 1. The laboratory used digital and manual entry from the requisition patient demographics data; however, the test requisition did not have any other information on the time of the sample collection. 2. On January 18, 2023, at approximately 1:15 p. m. The laboratory's GS, and TP affirmed that the laboratory did not have a complete test requisition that included time of sample collection for five (5) randomly chosen patients reviewed. 3. The laboratory testing declaration form, signed by the laboratory director on January 18, 2023, indicated that the laboratory performs approximately 122,000 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 review of the laboratory's records for policies and procedures, patient review records, proficiency testing reports, direct observation by the surveyors during the lab tour, and interviews with the general supervisor and testing personnel on January 18, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, and analytic phases of laboratory testing were monitored. See D2087, D3003, D3011, and D5305.