Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0895741	02/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Health Care Providers Laboratory	14411 Palmrose Ave, Baldwin Park, 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
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing records for the third event of 2020, ten (10) randomly selected patients from 11/22 /2019 to 12/10/2020, and interview with the technical supervisor (TS); it was determined that the laboratory failed to participate a testing event for Bacteriology and Virology which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained a score of 0% for Bacteriology and Virology testing during the third proficiency testing event of 2020 (Q3-2020). 2. The TS affirmed on February 1, 2021 at approximately 2:40 p.m. the unsatisfactory score of 0% obtained by the laboratory for Bacteriology and Virology analytes for Q3-2020. 3. Based on the annual test volume reported for 2020, the laboratory performed and reported approximately 69,821 Microbiology analytes.
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 second quarter (Q2-2020) event of the America Association of Bioanalysts (AAB) proficiency testing records, ten (10) randomly selected patients from 11/22/2019 to 12/10/2020, and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for General Immunology. The findings included: 1. For Q2-2020, AAB reported the following for anti-HAV Total and Anti-HBc IgG+ IgM: Analyte Score Reported Anti-HAV Total 60% Anti-HBc IgG+ IgM 0.0% 2. Based on the laboratory's annual testing declaration for 2020 the laboratory analyzed and reported approximately 26,775 General Immunology tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 02/01/2020 at approximately1:00 p.m. that the laboratory received the above unsatisfactory proficiency testing score.
D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing records for the third event of 2020, ten (10) randomly selected patients from 11/22/2019 to 12/10/2020, and interview with the technical supervisor (TS); the laboratory failed to participate a testing event for ANA which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained a score of 0% for ANA testing during the third proficiency testing event of 2020 (Q3-2020). 2. The TS affirmed on February 1, 2021 at approximately 1:30 p.m. the unsatisfactory score of 0% obtained by the laboratory for ANA for Q3-2020. 3. Based on the annual test volume reported for 2020, the laboratory performed and reported approximately 26,775 tests for the specialty of General Immunology.
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by:

	Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Urea Nitrogen (BUN) for the second Chemistry event of 2020 (Q2-2020). The finding included: 1. Based on review of PT records for Q2-2020, AAB reported an unsatisfactory score of 60% for the BUN test. The laboratory failed to report an acceptable test value for two (2) out of five (5) tested samples: Sample # Reported Intended range 6 28 26-32 7 20 20-24 8 25 23-28 9 33* 34-41 10 12* 14-18 2. Based on the laboratory testing declaration submitted at the time of the survey on 02 /01/2020 the laboratory analyzed and reported approximately 39,777 routine chemistry tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 02/01/2020 at approximately 2:15 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing records for the third event of 2020, ten (10) randomly selected patients from 11/22 /2019 to 12/10/2020, and interview with the technical supervisor (TS); it was determined that the laboratory failed to participate a testing event for all analytes in Routine Chemistry and Toxicology which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained a score of 0% for Routine Chemistry and Toxicology including the following analytes: ALT, Albumin, Alkaline phosphatase, amylase, AST, Total bili, Calcium, Chloride, Total Cholesterol, HDL, CK, Creatine, Glucose, Total Iron, Magnesium, Potassium, Sodium, Total Protein, Triglycerides, BUN, Uric acid, Carmamazepine, Digoxin, Phenobarbitol, Phenytoin, and Valproic acid testing during the third proficiency testing event of 2020 (Q3-2020). 2. The TS affirmed on February 1, 2021 at approximately 1:40 p.m. the unsatisfactory score of 0% obtained by the laboratory for all the Routine Chemistry and Toxicology analytes in (1) for Q3-2020. 3. Based on the annual test volume reported for 2020, the laboratory performed and reported approximately 70,200 tests for Routine Chemistry and 14, 034 tests for Toxicology subspecialty.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a

	proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing records and Corrective Action Forms (CAR) for unsatisfactory proficiency test scores, and interviews with the laboratory technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to undertake appropriate training, employ the technical assistance necessary to correct problems associated with the proficiency testing (PT) failures, and document remedial actions taken. The findings included: 1. The laboratory obtained unsatisfactory scores for the Chemistry analytes specified in D2088 and D2089. 2. Review of the documentation for CAR for the second quarter 2020 (Q2-2020) and third event 2020 (Q3-2020) of the AAB proficiency testing events, indicate the laboratory failed to provide appropriate training and document actions taken necessary to correct problems associated with PT failures. 3. The TS and TP affirmed on February 1, 2021 at approximately 3:00 p.m. that the laboratory failed to provide appropriate training for the testing personnel and document actions taken to correct problems associated with PT failures. 4. Based on the annual test volume reported for 2020, the laboratory performed and reported approximately 256,389 laboratory test annually.
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 reviews second quarter (Q2-2020) of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical supervisor (TS) and laboratory testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Testosterone analyte. The findings included: 1. Q2-2020, API reported an unacceptable score of 0% for testosterone. 2. For three (3) out of three (3) random patient sampling test results reviewed covering period from 03 /17/2020 to 11/23/2020, the laboratory analyzed and reported an unknown number of testosterone quantitative tests during the period the laboratory received the unsatisfactory proficiency testing score. 3. The TP confirmed on 02/01/2021 at approximately 1:00 p.m. that the laboratory received the above unsatisfactory proficiency testing score for testosterone.
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 COVID-19 Polymerase Chain Reaction (PCR) testing, and interviews with the technical supervisor (TS) and testing personnel (TP) on February 2, 2021 for its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures are not contained in closed systems for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. The findings included: 1. The laboratory performs PCR testing for the presumptive detection of SARS-CoV-2 using "TaqPath Covid-19 Combo Kit" 2. The TaqPath Covid-19 Combo Kit Instructions for use under Warnings and precautions states: "Use separate areas for the preparation of patient samples and controls to prevent false positive results. Samples and reagents must be handled in a biological safety cabinet" 3. During the laboratory tour on 02/01/2021 at approximately 11:30 a.m. the examiner observed that storage and preparation of reagents, RNA extraction, and PCR reaction using the QuantStudio were all performed in the same closed systems room. In addition, preparation of reagents for the PCR Master Mix cocktail was performed in an opened bench in the same room where the automated RNA extraction took place. 4. The TS and TP confirmed by interview on February 2, 2021 at approximately 11:45 a.m. that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in a biosafety cabinet in unidirectional flow rooms. 5. Based on laboratory records, the laboratory performed and reported approximately 43,640 Virology (COVID-19) molecular diagnostic tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation on the lack of protection of equipment and instruments from fluctuations and interruptions in electrical current and interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to provide protection of instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports . The findings included: 1. On the day of the survey, 02/01/2021 based on observation and interview with the TS and TP the laboratory failed to provide documentation for the instruments electrical fluctuation back up for the year 2020 in which electrical fluctuations and black outs occurred affecting proficiency and patient testing. 2. The TS and TP confirmed on 02/01/2021, at approximately 12:00 p.m. that the laboratory has no protection of equipment and instruments from fluctuations and interruptions in electrical current. 3. Based on the laboratory's submitted testing declaration volume for the year 2020, the laboratory tested and reported approximately 983 test daily.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyors' observation, examination of laboratory reagents, and interview with the technical supervisor (TS) and testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, 02/01/2021 at approximately 11:00 a.m., the examiner found the following expired vacutainers tubes in the phlebotomy room currently being used beyond its expiration date: Vacutainer Exp. Date Manufacturer SST Red Top 12/31/2020 BD Lithium Heparin 07 /31/2020 BD 2. The TS and TP affirmed on 02/01/2021 at approximately 11:10 a.m. using the vacutainers listed in (1) beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 149,080 Chemistry and General Immunology tests where the vacutainer tubes listed in (1) are used .
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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 observation, review of the laboratory records, and interview with the technical supervisor and laboratory testing personnel; it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to 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. The findings included: See D2021, D2075, D2077, D2089, D3005, D5413, D5417, and D6127.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review the laboratory's policies & procedures, proficiency testing performance records, lack of corrective action records and documentation, and

	interview with the technical supervisor, the laboratory director failed to ensure that an approved corrective action plan policy exists and is followed when any proficiency testing result is found to be unsatisfactory performance. The findings include: See D2094.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on observation of the laboratory layout for performance of molecular polymerase chain reaction (PCR), review of proficiency testing documents and policies and procedures, lack of corrective action reports documentation, lack of protection of instruments from fluctuations and interruptions in electrical current, and interviews with the technical supervisor (TS) and testing personnel; it was determined that the TS failed to ensure that patient test results were not reported until the test systems were functioning properly. See D2021, D2075, D2077, D2089, D2094, D3005, and D5413.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for competency assessments, and interview with the technical supervisor (TS); it was determined that the laboratory TS failed to perform and document the performance of one (1) out of two (2) testing personnel (TP) responsible for high complexity testing. The findings included: 1. There was no documentation to show that one (1) out of two (2) TP performing high complexity testing was evaluated during the first six months and annually thereafter. The evaluations must include but are not limited to the following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills 2. There were two (2) TP listed on the CMS 209 and LAB 116 forms that are performing high complexity testing, but no documentation of competency and evaluation for the year 2020 was performed for one (1) out of the two (2) TP. 3. The TS affirmed February 1, 2021 at approximately 4:00 p.m. that no competency assessments was performed and documented by the TS or laboratory director for TP1 performing high complexity testing. 4. Based on the laboratory's annual testing declaration submitted for 2020, the laboratory analyzed and reported 256,385 tests in the specialties for Microbiology, Diagnostic Immunology, Chemistry, and Hematology.