Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0895741	11/16/2018
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with the technical consultant (TC) and the testing personnel (TP), it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events in the specialty of General Immunology constituting unsuccessful PT performance. The findings included: See D-2084
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 laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed General Immunology including but are not limited to the following tests: ANA (anti nuclear antibody), HIV (anti-HIV-1 or 1/2 Screening), Rub (Rubella IgG. b. The laboratory enrolled its PT with AAB (American Association of Bioanalysts) PT provider to verify the accuracy of the General Immunology testing systems. c. The laboratory attained a score of 60% for ANA testing in the 1st 2017 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory attained a score of 40% for HIV testing in the 3rd 2017 PT event which was unsatisfactory analyte performance for the testing event e. The laboratory attained a score of 60% for HBsAg testing in the 3rd 2017 PT event which was unsatisfactory analyte performance for the testing event f. The laboratory attained a score of 60% for Rubella testing in the 3rd 2017 PT event which was unsatisfactory analyte performance for the testing event g. The laboratory performed ANA for patient samples in approximately 48 patient specimens monthly. h. The laboratory performed HIV for patient samples in approximately 383 patient specimens monthly. i. The laboratory performed Rubella for patient samples in approximately 13 patient specimens monthly. j. The laboratory performed HBsAg for patient samples in approximately 49 patient specimens monthly
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events which resulted in an unsuccessful performance. a. The laboratory performed General Immunology tests including but is not limited to the following tests: anti-HBc. b. The laboratory enrolled its PT with AAB (American Association of Bioanalysts) PT provider to evaluate the proficiency of testing performance and to verify the accuracy of the General Immunology testing systems. c. The laboratory attained scores of 0% for anti-HBc testing in both of the 3rd 2017 PT event and the 1st 2018 PT events, which resulted in an initial unsuccessful performance. Anti-HBc 3rd 2017 PT 0 % 1st 2018 PT 0 % d. The laboratory performed Anti-HBc for patient samples in approximately 27 patient specimens monthly. e. The laboratory consultant affirmed (10/12/18 @10:45 am) that

	the laboratory attained scores of 0% for anti-HBc testing in both of the 3rd 2017 PT event and the 1st 2018 PT events, which resulted in an initial unsuccessful performance.
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 laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed Routine Chemistry including but is not limited to the following tests: HDL b. The laboratory enrolled its PT with AAB (American Association of Bioanalysts) PT provider to verify the accuracy of the Routine Chemistry testing systems. c. The laboratory attained a score of 0% for HDL testing in the 1st 2018 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed HDL for patient samples in approximately 684 patient specimens monthly.
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 review of the laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed Endocrinology including but is not limited to the following test: TSH (Thyroid Stimulating Hormone) b. The laboratory enrolled its PT with AAB (American Association of Biocatalysts) PT provider to verify the accuracy of the Endocrinology testing systems. c. The laboratory attained a score of 40% for TSH in the 1st 2018 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed TSH for patient samples in approximately 270 specimens monthly. e. The laboratory affirmed (10/12/18 @ 12:30) that the laboratory attained a score of 40 % for TSH in the 1st 2018 PT event which was unsatisfactory performance.
D2121	HEMATOLOGY CFR(s): 493.851(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 laboratory's proficiency testing (PT) result reports, and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed CBC (Complete Blood Cell Count) including but are not limited to the following tests: WBC with automated cell Diff, RBC, Hgb (hemoglobin), Hct (Hematocrit) and Platelet count (Plt). b. The laboratory enrolled its PT with AAB (American Association of Biocatalysts) PT provider to verify the accuracy of the CBC testing systems. c. The laboratory attained a score of 0% for WBC with automated cell Diff in the 3rd 2017 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory attained scores of 0% for each of WBC, RBC, Hgb (hemoglobin), Hct (Hematocrit) and Platelet count (Plt).in the 1st 2018 PT event which were unsatisfactory analyte performance for the testing event. e. The laboratory performed CBC for patient samples in approximately 341 patient specimens monthly. f. The laboratory affirmed (10/12/18 @ 12:30 PM) that the laboratory attained scores of 0 % for WBC with automated cell Diff in the 3rd 2017 PT event and WBC, RBC, Hgb (hemoglobin), Hct (Hematocrit) and Platelet count (Plt).in the 1st 2018 PT event, respectively, which were unsatisfactory performance.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) result reports and interview with the technical consultant (TC) and the testing personnel, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of any test or procedure it performs that are not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory used instruments including Biorad Bioplex 2200, Roche Eclecsys to perform the analyte including, but are not limited to the followings: Ferritin, Folate, Homocystine, PSA, Testosterone, (TST), Vit B12 (B12) and E2, which are not listed in the subpart I of 42 CFR part 493. b. The laboratory enrolled the analyte mentioned above (item a) with AAB (American Association of Bioanalysts) PT provider to verify the accuracy of the testing systems. c. The laboratory attained scores 0% for the following analyte: Ferritin, Folate, Homocystine, PSA, TST, B12 in the 1st 2017 PT event which was unsatisfactory performance. d. The laboratory attained scores 50% for Estradiol (E2) in the 3rd 2017 PT event which was unsatisfactory performance. e. The laboratory failed to verify the accuracy of the testing system for Ferritin, Folate, Homocystine, PSA, TST, B12 and E2 at least twice annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records, and interview with the technical consultant, and the testing personnel, it was determined that the laboratory failed to performed and document calibration verification procedure at least once every 6 months including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system. The findings included: a. The laboratory failed to present the documents and evidences that in 2018 the laboratory performed and documented the calibration verification for the Routine Chemistry testing systems by Roche Cobas 6000 b. The laboratory affirmed (10/12/18 @ 13:10) that the laboratory failed to performed and documented the calibration verification for Routine Chemistry systems by Roche Cobas 6000 analyzer in 2018 to verify the laboratory's reportable range of test results for the test systems..
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's presidency testing (PT) records, and interview with the technical consultant, and the testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2075, D-2084, D-2087, D-2098, D-2121 and D-5217
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the technical consultant and the testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5439 and D-6016