Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0978885	**(X3) Date Survey Completed** 04/11/2019
Name of Provider or Supplier Premier Lab Solutions Sacramento	**Street Address, City, State** 4630 Northgate Blvd, Ste 150, Sacramento, 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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory test records for ten (10) randomly selected patients results from 07/07/2017 to 02/07/2019, proficiency testing (PT) result reports, and interview with the laboratory supervisor, it was determined that the laboratory failed to enroll and participate in a proficiency testing (PT) program that meets the criteria in subpart H of 42 CFR part 493 and is approved by HHS. The findings included: a. The laboratory performed bacteriology, routine chemistry, endocrinology, toxicology and hematology testing which is in the list of subpart I of 42 CFR part 493 using the BD Probe Tec ET, Beckman DxC, UniCel DxC, Access II and Sysmex CA series, Coulter UniCel DxH analyzers. b. The laboratory failed to show evidence of enroll in a PT program for bacteriology, routine chemistry, endocrinology, toxicology and hematology testing events using a CMS approved PT program for the first event (Q-1), 2017 and third event (Q-3), 2018 (which meets the criteria in subpart H of 42 CFR part 493). The laboratory analyzed and reported bacteriology, routine chemistry, endocrinology, toxicology (therapeutic drugs) and hematology (complete blood count (CBCD) and PT/PTT) patient test results during the approximate time of non-enrollment in a proficiency testing (PT) program; the PT 1st event (Q-1), 2017 for routine chemistry, endocrinology, toxicology and hematology and bacteriology and

	3rd event (Q-3), 2 018 for (C. trachomatis and N. gonorrhoeae) analytes. c. The laboratory supervisor confirmed 04/11/2017 13:00 (survey date) that patient test results were reported for the PT 1st event (Q-1), 2017 for routine chemistry, endocrinology, toxicology and hematology and bacteriology and 3rd event (Q-3), 2 018 for (C. trachomatis and N. gonorrhoeae) analytes yet the laboratory was not enrolled in an accredited PT program. d. The laboratory annual testing declaration (04 /11/2019) estimated the bacteriology, routine chemistry and endocrinology, toxicology and hematology estimated the total test volume as 2,360,501.
D2099	ENDOCRINOLOGY CFR(s): 493.843(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 API (American Proficiency Institute) proficiency reports (PT), review of ten (10) randomly selected patient result records from 07/07/2017 to 02/07/2019, proficiency testing (PT) results and interview with the laboratory technical supervisor, the laboratory failed to attain a score of at least 80 percent for thyroxine (TY). The findings included: a. API second event (Q-2) 2018 the laboratory received a proficiency testing score of 0% for the thyroxine (TY) analyte performed on the Beckman Access analyzer. Sample Reported Result Expected Result CH-06 18.6 12.1 - 18.3 CH-07 8.7 5.5 - 8.3 CH-08 12.3 7.6 - 11.5 CH-09 18.5 11.6 - 17.5 CH-10 24.6 13.4 - 20.3 c. The technical supervisor confirmed on 04/11/2019 15:00 (Survey date) that the laboratory had failed to attain a proficiency score of at least 80 percent for thyroxine (TY).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review and the lack of documentation of enrollment in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS, and interview with the laboratory supervisor, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the bacteriology, routine chemistry, endocrinology, toxicology and hematology analytes testing performed. (See D-2000)