Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2061756	02/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Central Valley Specialty	730 17th St, Modesto, 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 laboratory's proficiency testing result reports, and interview with the laboratory staff, 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 is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed routine chemistry testing, including but are not limited to the followings, Creatine (Cre), ALT/SGPT (ALT) and Blood gas pO2. b. In order to ensure the accuracy of the laboratory testing system annually, the laboratory enrolled its PT with API (American Proficiency Institute) PT programs. c. The laboratory attained scores of 40% for ALT and pO2 in the 1st 2017 PT event and a score of 20% for Cre in the 2nd 2017 PT event, which were unsatisfactory analyte performance for the testing events. d. The laboratory performed and reported test results of analyte Cre in approximately 500 patient samples monthly. e. The laboratory performed and reported test results of analyte ALT in approximately 39 patient samples monthly. f. The laboratory performed and reported test results of analyte pO2 in approximately 15 patient samples monthly. g. The laboratory staff affirmed (02/20/2018 @ 12:45 PM) that the laboratory failed to attained scores of at least 80 percent of acceptable responses for each analyte in each testing event were unsatisfactory analyte performance for the testing events.
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's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determine that the laboratory failed to verify, at least twice annually, the accuracy of any test or procedure it performed that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed TDM (Therapeutic Drug Management) testing including vacomycin, which is not listed in the subpart I of 42 CFR part 493. b. In order to ensure the accuracy of any test or procedure it performed, the laboratory elected to enroll a PT program provided by API. c. The laboratory attained a score of 40% for vancomycin in the 3rd 2017 PT event, which was unsatisfactory performance. d. The laboratory performed in approximately 20 patient samples monthly. e. The laboratory staff affirmed (02/20/2018 @ 13:45) that a score of 40% for vacomycin in the 3rd 2017 PT event was unsatisfactory performance.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the laboratory testing systems, review of the temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to follow the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system. The findings included: a. Observed a digital thermometer with a S/N 11284 and it was last calibrated in 12/2016 by RC, located in the equipment room. b. A past Max temperature was recorded at 9 oC which was out of the laboratory's acceptable range between 2 - 6 oC. c. Tried to reset and demonstrate how the features of this digital thermometer. d. It was noted that that thermometer did not work, after replaced a new battery. e. The laboratory staff the company's Bio Medical Engineering Department was in charge of the maintenance of the thermometer. f. The laboratory staff affirmed (02/20/2018 @10:45 AM) the thermometer was broken.
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 proficiency testing (PT) result reports, and

	interview with the laboratory staff, it was determine 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-2087 and D-5217
D6020	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 the quality control program is 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 proficiency testing (PT) result reports, and interview with the laboratory staff, it was determine that the laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided . The findings included: See D-5411