Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0885230	04/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
High Desert Medical Group	43839 15th St W, Lancaster, 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 third quarter (Q3-2017) American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results and interview with the technical consultant, 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. AAB reported unsatisfactory scores for the following analytes. Analyte: Score: Event/Year: Alk Phos 0% Q3-2017 PO2 60% Q3-2017 b. For six (6) out of eight (8) of random patient sampling test results reviewed covering period from 9/17 /2017 to 9/12/2018, the laboratory analyzed and reported Comprehensive Metabolic Panel (CMP) which included Alk Phos. Based on the laboratory's annual testing volume submitted the laboratory analyzed and reported 230 pO2 analytes during the time the laboratory received the above unsatisfactory testing scores. c. The technical consultant confirmed (4/10//2019, 12:30) that the laboratory received the above unsatisfactory proficiency testing scores.
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 second quarter (Q2-2018) of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results and interview with the technical consultant 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. Q2-2018, AAB reported unsatisfactory 0% score for Platelets. b. For eight (8) out of eight (8) random patient sampling test results reviewed covering period from 9/7/2017 to 7/15/2018, the laboratory analyzed and reported Complete Blood Count (CBC) analytes which included Platelets during the period the laboratory received an unsatisfactory proficiency testing scores for Platelets. c. The technical consultant confirmed (4/10//2019, 12:30) that the laboratory received the above unsatisfactory proficiency testing score.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on reviews of the American Association of Bioanalyts (AAB) proficiency testing records, random patient test results, and interview with the technical consultant , it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2087 and D 2121
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Critical Values policy and procedure, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory's testing personnel performing moderate complexity testing did not follow the laboratory's procedures for reporting critical value of patient test results. The findings included: a. The laboratory's Critical Values policy and procedure stated, " Document who, when, date and time that you spoke with the caregiver, then your initials. a. Critical Result called and read back by: ----at: on: ------ by: ----." b. For three (3) out of three (3) patient critical value test results reviewed covering period from 3/30/2017 to 4/10/2019, the laboratory testing personnel did not follow what the policy and procedure stated pertaining to calling and documenting Critical Value Results. c. The technical consultant confirmed (4/10/2019, 1230) that the testing personnel did not follow the above protocol in documenting critical results.