Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2066694	10/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Desert Medical Group, Inc	72605 Hwy 111 Ste A1, Palm Desert, 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 American Proficiency Institute (API) Proficiency Testing (PT) results 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 Troponin in two events were unsatisfactory analyte performance for the testing events. The finding included: a. The laboratory performed Troponin using Triage instrument, which is not listed in the subpart I of 42 CFR part 493. b. In order to ensure the accuracy of the testing of Troponin-i, the laboratory elected to participate a PT program offered by API to fulfill the requirement of "Evaluation of proficiency testing performance" 493.1236 annually. b. On the survey date of October 2, 2020 @ 11:05 AM, review of the API PT result reports from the 2018 3rd PT events thru the 2020 2nd PT events, the laboratory attained scores of 60 % and 40 % for 2nd 2019 PT and 3rd 2019 PT events, respectively for Troponin-i. c. The laboratory performed Troponin tests in approximately 44 patient samples each month. d. The laboratory staff affirmed on 10/2/2020 @ 11:10 am that the laboratory failed to attain PT scores at least 80 percent of acceptable responses for Troponin in the 2019 2nd and 3rd PT events.
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 American Proficiency Institute (API) Proficiency Testing (PT) results 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 RBC in the 1st 2019 PT event, which was unsatisfactory analyte performance for the testing event. The finding included: a. The laboratory used Horiba Micro 60 to perform CBC (complete blood cells count) and reported WBC with cell differentials, RBC, Hct., Hgb, Platelet count. b. In order to ensure the accuracy of the CBC test and meet the CLIA requirements, the laboratory elected to participate API PT program. c. On the date of survey, 10/02/2020 @11:10 AM, review of the API hematology PT testing results reports from the 3rd 2018 thru the 2nd 2020 PT event record, the laboratory attained a score of 60% RBC in the 1st 2019 API PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory attained a score of 20% D-dimer in the 3rd 2019 API PT event which was unsatisfactory analyte performance for the testing event. e. The laboratory performed CBC in approximately 130 patient samples each month. f. The laboratory performed D-dimer in approximately 11 patient samples each month. g. The laboratory staff affirmed on 10/02/2020 @ 11:15 AM that the laboratory failed to attain scores of at least 80 percent of acceptable responses for RBC and D-dimer in the 1st 2019 PT and 3rd 2019 PT events, respectively, were unsatisfactory analyte performance for the testing events.
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 American Proficiency Institute (API) proficiency testing (PT) reports from the 3rd 208 thru the 2nd 2020 PT events, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the API proficiency testing samples were tested as required under Subpart H of this part. The findings included: a. The laboratory performed and reported CBC, D-dimer, and Troponin-i, non-waived moderate complexity testing, for their patients onsite. b. In order to meet the CLIA requirements and to ensure the accuracy of the testing performance, the laboratory elected to participate in PT program offered by API for all the testing analytes listed above, (a). c. The laboratory failed to attain at least 80 % for Troponin-I, RBC and D-dimer which were unsatisfactory performance for the PT events, see D-2087 and D-2121.