Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2078669	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Legacy Md Medical Group Inc	222 E Cole Blvd, Calexico, 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 proficiency testing (PT) result reports, 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. The laboratory used Horiba Petra 400 to perform routine chemistry including but are not limited to the followings: Uric Acid, Cholesterol. b. The laboratory enrolled its PT with API (America Proficiency Institute) PT program to evaluate its proficiency testing performance for Petra 400 testing systems. c. The laboratory attained a score of 60 % for Uric Acid in the 2nd 2018 routine chemistry PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed Uric Acid in approximately 85 patient samples monthly. e. The laboratory affirmed (11/20/18 @ 11:30 am) that the laboratory attained a score of 60 % for Uric Acid in the 2nd 2018 routine chemistry PT event, which was unsatisfactory analyte performance for the testing event.
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 records, and interview with the technical consultant, it was determined that the laboratory failed to, at least twice annually, verify the accuracy of any test or procedure it performs that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed urine drug screen by using Horiba Petra 400 with Thermo Fisher Scientific reagents, b. The laboratory failed to perform and document the evaluation of the testing performance at least twice annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the technical consultant, it was determined that the laboratory director failed to review, approve, sign, and date the procedures or validation documents before use. The findings included: a. At the time of the survey (11/20/18 @ 11:55 AM), the laboratory director did not sign and date the validation documents for urine drug screen by Horiba Petra 400 analyzer. b. The technical consultant affirmed (11/20/18 @ 11:55 AM) that the validation documents for urine drug screen testing by Horiba Petra 400 analyzer were not approved, signed, and dated by the current laboratory director.
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 proficiency testing (PT) result reports, and interview with the technical consultant, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2087
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 records, and interview with the technical consultant, it was determined 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-5407, and D-5217