Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2078669	07/23/2024
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the America Proficiency Institute (API) and the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D for the years 2023 and 2024 the laboratory obtained unsuccessfully score for testosterone analyte for three consecutive events, see D2099 for endocrinology subspecialty and routine chemistry (sodium analyte) in which the laboratory is certified under CLIA. SeeD2087 and D2096.
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 America Proficiency Institute (API) proficiency testing (PT) records, six (6)) randomly selected patient results, and interview with the technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Routine Chemistry various analytes. The finding included: 1. Based on review of PT records from API the following unsatisfactory results were obtained for: a) Amylase, first event in 2024 (Q1-2024) = 40% b) Chloride, Second event 2024 (Q2-2004) = 40% c) Folate, Second event 2024 (Q2-2004) = 0% d) Sodium, Third event 2023 (Q3-2023) = 60% d) Sodium. Second event 2024 (Q2-2004) = 0% 2. Based on the laboratory testing declaration submitted at the time of the survey on July 23, 2024, the laboratory analyzed and reported approximately 70,000 Routine Chemistry tests including the analytes in #1 above during the time the laboratory had unsatisfactory proficiency testing results. 3. The TC affirmed on 7/23/2024 at approximately 11:45 a.m. that the laboratory received the above unsatisfactory proficiency testing score from API.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) and the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API evaluation reports, the laboratory failed to achieve satisfactory performances in 2023 and 2024 in two out of three consecutive testing events for sodium analyte. The finding included: 1. Third Event 2023 (Q3-2023) Sodium 60% 2. Second Event 2024 (Q1-2024) 0%
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 review of the America Proficiency Institute (API) proficiency testing (PT) records and the Certification and Survey Provider Enchanced Reporting (CASPER) Report 0155D Individual Laboratory Profile , six (6) randomly selected patient results, and interview with the technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Endocrinogy testosterone analyte. The finding included: 1. Based on review of PT records from API the following unsatisfactory results were obtained for testosterone analyte: a) Third event of 2023 (Q3-2023) 0% b) First event of 2023 (Q1-2024) 0% c)

	Second event of 2024 (Q2-2024) 50% for testosterone analyte. 2. Based on the laboratory testing declaration submitted at the time of the survey on July 23, 2024, the laboratory analyzed and reported approximately 5,000 Endocrinology tests including testosterone analyte during the time the laboratory had unsatisfactory proficiency testing results. 3. The TC affirmed on 7/23/2024 at approximately 11:45 a.m. that the laboratory received the above unsatisfactory proficiency testing score from API.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures for all tests performed in the laboratory (Virology, General Immunology, Routine Chemistry, Endocrinology and Hematology) and interviews with the technical consultant (TC) laboratory testing personnel (TP); it was determined that the laboratory failed to have available and follow written procedures for all test performed in the laboratory. The findings included: 1. On the day of the survey on July 23, 2024, at approximately 12:15 p.m. the laboratory failed to provide written policies and procedures for all test performed in the laboratory. 2. The TC and TP confirmed on 7/23/2024 at approximately 12:30 p. m. that the laboratory did not have written policies and procedures available for all tests performed in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 7/23/2024, the laboratory processed and reported 112,000 patients' sample without having a procedure each diagnostic test performed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory's tour of reagent materials used in the laboratory and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to label various reagents used for test performance to indicate the reagent's received date, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on July 23, 2024, at approximately 1:30 pm.; no received date, opening, preparation, or expiration date labels were used or documented for all test reagents used throughout the laboratory. 2. The laboratory's TC and TP affirmed in an interview conducted on July 23, 2024, at approximately 2:00 p.m. that all the reagents used in the laboratory were not labeled with the received date, opening, preparation, and expiration dates or

	documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 112,000 for which testing reagents were not labelled.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, lack of a policy and a list of critical values for all tests performed in the laboratory including hematology and chemistry and its reporting procedure, review of six (6) randomly selected patient sampling test results and interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to have and follow a policy for reporting of critical values. The findings included: 1. The laboratory's policy and procedure manual did not have a critical results notification policy, neither was a list of established critical values for all tests performed in the laboratory. 2. For two (2) out of six (6) patients results reviewed there was no documentation notes on how critical values were handled and reported by the TP. 3. The TC and TP affirmed on July 23, 2024, at approximately 1;45 p.m. that the laboratory did not have a written policy and procedure on critical values documentation for reporting.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the proficiency testing reported results review of the American Proficiency Institute and the CASPER 155 report American Proficiency Institute records for 2023 third event and 2024 first and second event, the laboratory director failed to provide overall management and a direction of the laboratory services. Refer to D 2087 and D6016.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)

	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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, six (6) randomly selected patients tests records, lack of laboratory test procedures, and interview with the technical consultant and testing personnel (TP); it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic and analytic phases of the laboratory testing were monitored. See D5401, D5415, D5417, D5813.
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 the proficiency testing report review of the American Proficiency Institute and the CASPER 155 report records for 2023 and 2024 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2087, D2096, and D2099.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on direct observation and interview with the technical consultant and testing personnel; it was determined that the laboratory director failed to ensure that a signed and dated approved written procedure manual is always available to all personnel responsible for any aspect of the testing process. See D5401.

D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on the lack of laboratory's policies and procedures, reagents labels, expired reagents stored in the laboratory, lack of critical values list, failed proficiency testing for various analytes, and interview with the laboratory testing personnel it was determined that the technical consultant failed to identify the training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed. The findings included: D2099, D5415, D5417, and D5813.