Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0891753	09/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Saddleback Medical Group Inc	24221 Calle De La Louisa Ste 200, Laguna Hills, 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
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 API (American Proficiency Institute) proficiency testing (PT) 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 Free T4. The findings included: a. The laboratory performed endocrinology including but not limited to Free T4. b. The laboratory enrolled with API PT program to ensure the accuracy of the testing results. c. The laboratory attained a score of 0% for Free T4 in the Q3 2021 PT event was unsatisfactory analyte performance for the testing event. d. The laboratory performed in approximately 457 patient samples monthly. e. The laboratory staff affirmed (9/16/22 @ 10:55 am) that the laboratory attained a score of 0% for Free T4 in the Q3 2021 PT event was unsatisfactory analyte performance for the testing event.
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 API (American Proficiency Institute) proficiency testing (PT) 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 Blood Cell Identification (Cell ID) for Q1 2022 hematology PT was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Coulter Act Diff2 system to perform complete blood cell counts (CBC) including but not limited to automated blood cell differentials (Cell ID) and enrolled its PT with API to verify the accuracy, reliability, and timely of the patient test results. b. The laboratory failed to attain a score of at least 80 percent of acceptable responses for Cell ID for Q1 2022 hematology PT was unsatisfactory analyte performance for the testing event. c. The laboratory performed CBC and report automated Blood Cell Identification in approximately 910 patient sample monthly. d. The laboratory staff affirmed (9/16/2022 @ 10:55am) that the laboratory failed to attain a score of 80% for automated Blood Cell ID
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 API (American Proficiency Institute) proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory, at least twice annually, the laboratory failed to verify the accuracy of any test or procedure it performed that are not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed the following tests the following tests: CRP (hs), CRP (quant), Ferritin, PTH, Testosterone (TST) and Vitamin D, which are not listed in subpart I of 42 CFR part 493, b. The laboratory elected to enroll with API to ensure accuracy of the patient test results for evaluation of proficiency testing performance at least twice annually c. The laboratory failed to attain scores of at least 80 percent of acceptable responses for the analytes listed at (a) in various PT event as follows: Test = analyte PT Score and Event Vol = Estimated Volume Analyte Score (%) Event Vol (monthly) CRP (hs) 0 Q1 22 51 CRP (quant) 50 Q3 21 51 Ferritin 50 Q1 21 115 PTH 0 Q3 21 158 PTH 0 Q1 22 TST 50 Q1 22 16 Vit D 50 Q1 22 410 d. The laboratory staff affirmed (9/16/2022 @ 11 am) that the laboratory failed to attain a score of 80% for the analyte listed in item (c) with an estimated monthly test volumn were unsatisfactory analyte performance for those testing event.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

	by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review the laboratory's records, and interview with the laboratory staff, it was determined that the laboratory failed to perform and document calibration verification procedure including, but not limited to use at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system, and at least once every 6 months. The findings included: a. The laboratory used Hitachi Cobas 6000 to perform routine chemistry equipped with ISE including but not limited to the following tests: Albumin, Glucose, Calcium, Cholesterol, Triglyceride. b. The Cobas 6000 system uses one or two calibrators to perform calibration for each analyte. c. The laboratory failed to perform calibration verification for routine chemistry in 2021 and 2022. d. The laboratory staff affirmed (9/12/2022 @ 11:45 am) that the laboratory did not have documentations of calibration verification for the years of 2021 and 2022.
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 records, API (American Proficiency Institute) proficiency result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples, and evaluation of proficiency testing performance at least twice annually were tested as required. The findings included: a. The laboratory performed routine chemistry, hematology, and endocrinology. b. The laboratory enrolled with API PT programs to ensure accuracy for all the tests performed. c. The laboratory director failed to ensure that the proficiency testing samples were tested as required (see D-2098, D-2121 and D-5217).