

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0891753	(X3) Date Survey Completed 10/23/2020
Name of Provider or Supplier Saddleback Medical Group Inc	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's API (American Proficiency Institute) proficiency testing (PT) results reports from the 3rd 2018 thru partial 3rd 2020 PT records, and the laboratory records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to verify the accuracy of Glycated Hemoglobin (A1c), LDL (measured), CRP (quant), and Sedimentation Rate (ESR) that the laboratory performed analyte which were not included in subpart I of this part, 42 CFR part 493. The findings included: a. The laboratory performed analyte in the subspecialties of chemistry, diagnostic immunology, and hematology, including but are not limited to the followings: glycated hemoglobin (A1c), LDL (measured) (LDL), CRP (quant) (CRP), and ESR. b. In order to meet the CLIA regulations, to verify and to ensure the accuracy of any test or procedure the laboratory performed that is not included in subpart I of 42 CFR part 493. c. The laboratory elected to enroll API (American Proficiency Institute) PT programs to verify the accuracy of their testing procedures. d. On 10/23/2020 @ 11:40 AM reviewed the laboratory API PT testing results reports from the 3rd 2018 thru a partial 3rd 2020 PT result reports. e. The laboratory attended scores of 0 % and 40% for analyte of A1c and LDL for the 2nd and the 3rd 2020 PT events which were unsatisfactory test performance. f. The laboratory attended scores of 50 % the analyte of CRP for the 1st 2020 PT event which was unsatisfactory test performance. g. The laboratory attended scores of 50 % the analyte of ESR for both 3rd 2019 and the 2nd 2020 PT events which were unsatisfactory test performance. h. The laboratory performed the analyte of A1c, LDL (using HDL counts), CRP and ESR in approximately 524, 690, 45, and 73, patient samples each month, respectively. i. The laboratory personnel affirmed on 10/23/2020</p>

@ noon that the laboratory failed to attend at least 80% of each analyte mentioned above (d) (e) and (f) in various PT events, which were unsatisfactory test performances.

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 proficiency testing (PT) results reports from 3rd 2018 thru part 3rd 2020 PT records, and the laboratory records, and interview with the laboratory testing personnel, 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: a. The laboratory performed analyte in the subspecialties of chemistry, diagnostic immunology, and hematology, including but are not limited to the followings: glycated hemoglobin (A1c), LDL (measured) (LDL), CRP (quant) (CRP), and ESR. b. The laboratory affirmed on 10/23/2020 @ noon that the laboratory failed to attend at least 80% of the analyte of A1c, LDL, CRP, and ESR, in various API PT challenges, see D-5217, which were unsatisfactory test performances.