Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0981428	(X3) Date Survey Completed 06/30/2023
Name of Provider or Supplier Samir Anabi Md / Anabi Medical Corp	**Street Address, City, State** 160 E Artesia St Ste 225, Pomona, 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 personnel, 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 was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory attained a score of 40% for FT4 which was less than 80% of acceptable responses for API Endocrinology 1st 2023 PT event which was unsatisfactory analyte performance for the testing event. b. The laboratory performed FT4 in approximately 66 patient sample monthly c. The laboratory personnel affirmed (6/30/2023 @ 12:35 PM) that the laboratory failed to attain a score of at least 80 percent of acceptable responses for FT4 in API endocrinology 1st 2023 PT event 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's API (American Proficiency Institute) proficiency testing (PT) result reports, and interview with the laboratory personnel, it was

	determined that the laboratory failed to verify the accuracy of the tests it performed that were not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed PSA, Testosterone (TST), and 25-OH Vitamin D (25-OH) and enrolled its evaluation of proficiency testing performance with API PT program to verify the accuracy of the testing procedures. b. The laboratory failed to perform, at least twice annually, evaluation of proficiency testing performance to verify the accuracy for the test procedures mentioned above (a). c. The laboratory attained scores of less than 80% for the following analytes: Event Analyte Result (%) 3rd 2022 PSA 50 3rd 2022 TST 0 3rd 2022 25-OH 0 1st 2023 25-OH 50
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 API (American Proficiency Institute) proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory performed FT4, which is included in the subpart I of 42 CFR part 493 and the laboratory enrolled its PT program with API (American Proficiency Institute) to ensure the accuracy of FT4 testing procedure. b. The laboratory attained a score of 40% which was less than 80 percent of acceptable responses for FT4 in API endocrinology Q1 2023 PT event was unsatisfactory analyte performance for the testing event (see D-2098) c. The laboratory performed PSA, Testosterone, 25-OH Vitamin D which are not listed in subpart I of 42 CFR part 493 and failed to attain at least 80 percent of acceptable responses in PT events was unsatisfactory analyte performance (see D-5217)