Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0936324	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rancho Santa Fe Medical Group, Inc	3230 Waring Ct Ste Q, Oceanside, 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	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 proficiency testing (PT) test result reports and interview with the laboratory staff, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of iCa (ionized Calcium) by i-Stat device. The findings included: a. The laboratory uses i-Stat device to perform Chem 8 testing which includes but not limited to iCa (ionized Calcium). b. The laboratory elected to enroll with API (American Proficiency Institute) PT program to verify the accuracy for Chem 8 testing. c. The laboratory obtained a 0% for iCa in the Q1 2022 API chemistry PT event, which was unsatisfactory performance. d. The laboratory performed i-Ca in approximately 48 patient specimens monthly. e. The laboratory staff affirmed (8/25/2022 @ 10:25 am) that the laboratory obtained a score of 0% for iCa in the Q1 2022 API chemistry PT event, which was unsatisfactory performance.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to demonstrate and document that the laboratory can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy. (B) Precision., (C) Reportable range of test results for the test system, (D) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings included: a. The laboratory used i-Stat to perform Chem 8 and report iCa, BUN, Glucose, Creatinine, Chloride, Sodium, Potassium, TCO2, Hematocrit and Hemoglobin (calculated). b. The laboratory failed to validate the i-Stat device and demonstrate that the laboratory can obtain performance specifications of i-Stat device comparable to those established by the manufacturer.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's EQC (Equivalent Quality Control) for quality control procedures, and interview with the testing personnel, it was determined that the laboratory failed to establish a quality control procedure which can (1) detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance, (2) monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance, and (3) document all control procedures performed. The findings included: a. The laboratory used i-Stat device to perform Chem 8 testing and established EQC (Equivalent Quality Control) procedures. b. There were no QC records available at the time of survey (8/25/22 @11:37 am) for i-Stat devices. c. The laboratory failed to either adapt IQCP (Individual Quality Control Plan, effective of 1/1/2016) or establish CLIA regular QC procedures for at least two levels (low and hi) of external control materials each day of the patient testing or following the i-Stat manufacturer's instructions. d. The laboratory failed to document all control procedure performed.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported

	from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test result reports, and interview with the testing staff, it was determined that the laboratory failed to provide an electronic system(s) in place to ensure test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. The findings included: a. The laboratory used Info HQ, an electronic system as a Laboratory Information System (LIS). b. The patient test result report provided a "Flag" column where to indicate an "abnormal" (Abn) result. b. Review of 6 patient test result reports as follows, with test results were abnormal according to the laboratory established "Reference Range". No flagging identified and shown in the patient test result reports: Date ID Abn Tests 8/4 /22 063034 Glu, 140, Hct 29, 8/11/22 081122 TCO2 21 Hct 37 7/6/22 010355 Glu 151 8/5/22 061826 Glu 124 Hct 34 6/20/22 120731 Glu 118 Hct 36 8/8/22 021651 Glu 309 Crea 1.4.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, proficiency testing (PT) test result reports, EQC quality control procedures, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to ensure accuracy, reliability, and timely of the patient test result reports. The findings included: a. The laboratory used i-Stat device to perform Chem 8 testing and reported iCa, BUN, Creatinine, Chloride, Sodium, Potassium, TCO2, Glucose, Hematocrit and Hemoglobin (calculated) b. The laboratory director failed to ensure that the quality control and quality assessment programs were maintained to ensure accuracy, reliability and timely of the patient test result reports (see D-5217, D-5421, D-5441, and D-5801)