Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2117632	08/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
California Rheumatology & Wellness	7082 N Maple Ave Ste 101, Fresno, 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
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 first quarter (Q1-2017) of the American Proficiency Institute (API) performance summary report, random patient sampling records and interview with the testing personnel, it was determined that; the laboratory failed to attain a score of at least 80 percent of acceptable responses for Erythrocytes (RBC) and Hematocrit (HCT) analytes. The findings included: a. Q1-2017, API reported the following unsatisfactory proficiency testing scores; Analyte: Score: Event/Year: RBC 60% Q1/2017 HCT 60% Q1-2017 b. For seven (7) out of seven (7) random patient test reports reviewed covering period from 12/18/2017 to 6/18/2019, the laboratory analyzed and reported Complete Blood Count (CBC) during the approximate time the laboratory received the unsatisfactory scores. c. The testing personnel confirmed (8/22 /1029, 1500) that the laboratory received the above unsatisfactory scores. d. Based on the laboratory's annual testing declaration submitted for 2017-2019 the laboratory analyzed and reported approximately 7,800 CBC's which included the RBC counts and HCT analytes.
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 first quarter (Q1-2017) of the American Proficiency Institute (API) performance summary report, random patient sampling records and interview with the testing personnel, it was determined that; the laboratory failed to 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. a. Q1-2017, API reported the following unsatisfactory proficiency testing scores; Analyte: Score: Event/Year: MCH 40% Q1/2017 MCHC 40% Q1-2017 Note: Abbreviations: MCH (Mean Corpuscular Hemoglobin) MCHC (Mean Corpuscular Hemoglobin Concentration) b. For seven (7) out of seven (7) random patient test reports reviewed covering period from 12/18 /2017 to 6/18/2019, the laboratory analyzed and reported Complete Blood Count (CBC) during the approximate time the laboratory received the unsatisfactory scores. c. The testing personnel confirmed (8/22/1029, 1500) that the laboratory received the above unsatisfactory scores. d. Based on the laboratory's annual testing declaration submitted for 2017-2019 the laboratory analyzed and reported approximately 7,800 CBC's which included the MCH and MCHC analytes.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of random patient sampling test results, the laboratory's policy and procedure manual and interview with the testing personnel, it was determined that; the laboratory failed to follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. The findings included: a. The laboratory's policy and procedure manual for EDTA Specimens stated: "The ICSH (international Committee for Standardization in Hematology) defines fresh blood specimens as processed within four hours after collection. Whole blood collected in EDTA provides accurate results for all parameters within eight hours of collection. The white cell size distribution may shift when specimens are run between 5 and 25 minutes after collection or more than eight hours after collection-this may affect the automated differential results, and cause instruments flags. Samples are mixed on hematology rocker while awaiting analysis in the laboratory." b. For four (4) out of six (6) random patient test results reviewed covering period from 12/19/2017 to 6/18/2019, three patients were analyzed and reported more than the specified policy and procedure by the laboratory. Following are patient examples: Patient #1 Collection Date/Time : 12/18/2017/10:32 AM Received Date/Time: 12/19/2017/01:17 PM Analyzed Date/Time: 12/19/2017/01:39 PM Patient #2 Collection Date/Time : 04/12/2018/09:32 AM Received Date/Time: 04 /12/2018/09:32 AM Analyzed Date/Time: 04/13/2018/01:08 PM Patient #3 Collection Date/Time : 07/25/2018/10:30 AM Received Date/Time: 07/27/2018/08:59 AM Analyzed Date/Time: 07/27/2018/8:31 AM Patient #4 Collection Date/Time : 07/07 /2019/03:28 AM Received Date/Time: 01/08/2019/10:36 AM Analyzed Date/Time: 01 /08/2019/11:25 AM c. The testing personnel confirmed (8/22/2019, 1500) that the laboratory did not follow its policy and procedure regarding specimens handling processing, test analyses.