Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2103045	07/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pm Pedicatrics Of California,	18555 Ventura Blvd Ste B, Tarzana, 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 American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test result and interview with the laboratory director, 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. The findings included: a. AAB reported the following unsatisfactory proficiency testing scores for C - reactive protein (CRP) test. Analyte: Score: Event/Year: CRP 0% Q1-2016 CRP 50% Q2-2017 b. For one (1) out of one (1) random patient test result reviewed (10/5/2017), the laboratory analyzed and reported CRP during the approximate time the laboratory's proficiency testing scores were unsatisfactory. c. The laboratory director affirmed (7/2/2018, 12N) that the laboratory received the above unsatisfactory proficiency testing scores. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by:

	Based on review of random patient test results, and interview with the laboratory director it was determined that the technical consultant and or the laboratory director failed to establish a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. See D5779, and D6070.
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 test results, laboratory's Critical Values policy and procedure, and interview with the laboratory director, it was determined that the individual performing moderate complexity testing did not 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 Critical Values Policy stated: "The following results are considered to be Critical Values. Must be repeated for confirmation. The first report must be used as the final report. Archive and document actions taken, on appropriate log or the instrument print out. Keep both reports, final result should indicate that the results were verified by repeat analysis." b. For one (1) out of six (6) random patient test results reviewed covering period from 10/5/2017 to 5/17/2018, one (1) patient had a high result of White Blood Cell (WBC) count which fall into the category as critical value and yet it was not repeated as the laboratory critical values policy indicated. c. The laboratory director affirmed (7/2/2018, 12N) that the laboratory did not follow its own policy regarding repeat analysis.