Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0598778	02/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Palo Alto Medical Foundation	3200 Kearney St, Bldg 1 Fl 1, Fremont, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the first quarter (Q1-2017) Sperm count, second quarter (Q2-2017) Sperm motility of the American Association of Bioanalyts (AAB) proficiency testing records and interview with the technical supervisor, it was determined that the laboratory failed to verify the accuracy of the above analytes with an artificial score of 100%. The findings included: Q1-2017 a. AAB reported the following artificial score of 100% proficiency testing scores. Analyte: Value Acceptable Sperm Reported: Range: Count Spec#1 21 4-18 Q2-2017 Analyte: Value Acceptable Sperm Reported: Range: Motility Spec#1 21 34-58 b. Based on the laboratory's annual testing volume declaration submitted for 2016-2017, the laboratory analyzed and reported 568 Sperm analysis even though the laboratory's proficiency testing scores were unsatisfactory for sperm count and sperm motility. c. The testing personnel affirmed (2/21/2018, 1400), that the laboratory received the above artificial 100% for the above analytes without any corrective actions taken by the laboratory.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review and the lack of documentation of a corrective action when the laboratory receives an artificial 100% scores for proficiency testing results and interview with the technical supervisor, it was determined that the laboratory has not established and document corrective action for an artificial 100% proficiency testing scores. See D 5215.