Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2118791	12/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Don Mehrabi Md Apmc	1505 Wilson Terrace, Ste 240, Glendale, 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
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 the surveyor's observation, review of the laboratory quality control (QC) records, log of patients' results, lack of QC policy and procedure, and interview with the testing personnel (TP); it was determined that the laboratory failed to establish quality control procedures that monitor the accuracy and precision of the complete analytic process including the number, the type, and the frequency of the QC materials when performing KOH and wet mounts microscopic examinations. 1. On the day of the survey December 3, 2021 at approximately 11:00 a.m., the surveyor observed that QC was not performed and documented whenever Mycology KOH and Parasitology wet mount procedures were performed. 2. For seven (7) out of seven (7) random patient test results reviewed on the patient log for macroscopic examinations performed, no QC was performed or documented, neither was documented who performed and reported the results for Mycology and Parasitology. 4. The TP confirmed on December 13, 2021 that the laboratory lacked an established policy and procedure for QC when microscopic examinations were performed for Mycology (KOH) and Parasitology (wet mounts).

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of random patient testing records, quality control data, policies and procedures, and interviews with the testing personnel; it was determined that the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality control as they occur. See D5441.