Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1062719	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Consultants Amedical Corp	28078 Baxter Rd Ste 140, Murrieta, 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
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the laboratory personnel, it was determined that the laboratory failed to follow the manufacturer's instruction to perform instrument calibration based upon the performance specifications verified and established preciously. The findings included: a. The laboratory used ABX Micro 60 to perform complete blood cell count (CBC) including but not limited to White blood cell count (WBC) and automated WBC cell differentials, Red blood cell (RBC), hemoglobins, etc. b. The laboratory failed to follow the manufacturer instructions to perform calibration at the frequency of every 6 months in 2018 and 2019. c. The laboratory personnel affirmed (9/24/2019 @ 10:50 am) that the laboratory failed to perform ABX micro 60 instrument calibrations according to the manufacturer' instruction.
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 observation of the instrument quality control (QC) data management, review of the laboratory's QC records, and interview with the laboratory personnel, it was determined that the laboratory failed to monitor overtime 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. The findings included: a. The laboratory performed three levels of QC, namely Low, Norm, and High, for its ABX Micro 60 hematology analyzer following the manufacturer's instructions. b. Review of the laboratory's Levey-Jennys (L-J) chart between 9/9/19 and 9/20/19 for WBC. c. The L-J chart showed 6 out of total of 8 fallen between 1SD and 2SD in a positive bias higher shift for Norm and High QC levels. d. The laboratory failed to detect its positive QC bias for WBC and failed to take actions to assess and evaluate the outcome.