Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0997753	01/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Best Medical Options	Barrio Mameyal Carr 698, Dorado, PR	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration records review, manufacturer's instructions and laboratory general supervisor interview on January 3, 2019 at 11:00 A.M., it was determined that the laboratory failed to perform the calibration procedures with at least the frequency recommended by the manufacturer (annually) for the hematology tests performed by the Sysmex KX-21N system. The findings include: 1. The laboratory uses a Sysmex KX-21N hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that a calibration is to be performed by a Sysmex technical service representative on an annual basis. 3. From January 2017 to December 2018, the calibration records showed that the laboratory did not perform at least annually the calibration procedures for the Sysmex KX-21N hematology system. The last calibration verification for Sysmex KX-21N system was performed on October 2017. 4. The laboratory general supervisor confirmed on January 3, 2019 at 11:00 A.M., that the laboratory failed to perform annually the calibration procedures for Sysmex KX-21N system.

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 calibration records review, manufacturer's instructions and laboratory general supervisor interview on January 3, 2019 at 11:00 A.M., it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1.The laboratory failed to perform the calibration procedures with at least the frequency recommended by the manufacturer (annually) for the hematology tests performed by the Sysmex KX-21N system. Refer to D5437.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on calibration records review, manufacturer's instructions and laboratory general supervisor interview on January 3, 2019 at 11:00 A.M., it was determined that laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory failed to perform the calibration procedures with at least the frequency recommended by the manufacturer (annually) for the hematology tests performed by the Sysmex KX-21N system. Refer to D5437.