Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0541553	10/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Leo E Orr Md	1245 Wilshire Blvd Ste 801, Los Angeles, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Association of Bioanalysts (AAB) and interview with the laboratory testing person #1 on October 22, 2021 at 11:15 am, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, Platelets, Lymphocyte % and Neut/Gran % at the 3rd event of 2020. The findings include: 1. The laboratory performed complete blood count (CBC) using an automated Cell-Dyn 1800 instrument. To verify its test accuracy, the laboratory participated AAB PT testing for the year of 2020. However, it received a score of 60% at the 3rd event for the following analytes: Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, Platelets, Lymphocyte % and Neut/Gran % resulting in an unsatisfactory analyte performance for the event. Therefore, the failure in the PT event suggesting that the patients' results reported during the PT event period might had not been accurate and thus causing patient harm. 2. The laboratory testing person #1 on October 22, 2021 at 11:15 am, affirmed that the laboratory had received a score of 60% at the 3rd event for the following analytes: Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, Platelets, Lymphocyte % and Neut/Gran %. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/22/2021, stated that the laboratory performs 1,200 CBC tests, annually.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure and AAB PT and QC records and interview with the laboratory testing person #1 on October 22, 2021 at 11: 35 am, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D2121 and D6042.
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 Surveyor review of laboratory's policy & procedure, quality control (QC) data, and interview with the laboratory testing person #1 on October 22, 2021 at 11:05 am, the technical consultant failed to establish the parameters for acceptable levels of analytic performance of QC resulting too many repeats after QC failure. The findings include: 1. The laboratory performed complete blood count (CBC) using an automated Cell-Dyn 1800 instrument. On 01/28/2021, the laboratory ran HICTRL1 QC for a total of 9 times spanning from 10:46 - 11:38 am until all the QC were within the acceptable range at the last run. On the other hand, the laboratory ran 3 patients' sample on the same day for 1 time. Without having an established QC parameter, the testing person repeated the QC run 9 times until the QC were acceptable. 2. The laboratory testing person #1 on October 22, 2021 at 11:05 am, affirmed that the technical consultant did not establish QC repeat policy. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/22/2021, stated that the laboratory performs 1,200 CBC tests, annually.