Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0550065	04/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
William A Pullen Md	1301 20th St, Ste 550, Santa Monica, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the Abbott Cell-Dyn 1800 hematology analyzer quality control (QC) record review, ten (10) random patient sampling covering the period from 01/30/2017 to 01/31/2018 and technical supervisor interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. The findings included: a. On 04/30/2018 (survey date), it was found that the laboratory was not following their quality control (QC) policies and procedures under "Section: Quality control Policy - General" and "Section: Quality Control Decisions". From 09/06/2017 through 04/12/2018 the laboratory periodically had exceeded their shifts and trends criteria policies for rejection of control results. During this period the quality controls used on the Abbott Cell-Dyn 1800 hematology analyzer for platelets (Plt) periodically had exceeded the reference ranges, continuously repeated and yet no corrective actions were noted on the QC data reports. Quality control failures which appeared as manual entry errors (sample run under wrong control) or sampling errors (short sample, etc.) were not documented with corrective actions. Also, quality controls that did not meet the acceptable criteria were deleted from the levy-Jennings graph, yet no corrective actions responses were documented. b. On 04/30/2018 the technical consultant affirmed that periodically no documentation was recorded for ongoing quality control mechanism to monitor, assess, and correct problems when identified. c. The laboratory testing declaration (04/30/2018) estimated an annual hematology patient testing volume of 16,632.

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 review 04/31/2018 (survey date) of the lack of quality control (QC) records, a random sampling of ten (10) patient test reports from 01/30/2016 to 01/31/2018, performance specification records, and interview with a technical consultant, it was determined that the laboratory failed to establish a quality control program appropriate for testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that those levels were maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. Also, ensuring that patient test results are not reported until all corrective actions have been documented and the test system is properly functioning. (See D5791)