Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0696103	08/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Anatoly Belilovsky Md, Pllc	2964 Brighton 6th Street, Brooklyn, NY	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on surveyor's review of the Proficiency Testing (PT) Accutest PT summary reports& result records for the three PT test events in 2020. Confirmed in an interview with the technical consultant, the laboratory failed to perform PT testing on the second Abbott Emerald hematology analyzer in 2020, which is used routinely for patient testing. FINDINGS: The technical consultant confirmed on August 25, 2020 at approximately 2:30, the surveyor's findings that the laboratory laboratory failed to perform PT testing on the second Abbott Emerald hematology analyzer in 2020, which is used routinely for patient testing. a. the laboratory performed 2020 hematology PT samples for all three events only on the first Abbott Emerald. b. the laboratory did perform patient testing on both hematology analyzers from 1/1/2020 through 12/30/21.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a surveyor's review of the validation records for the ABX Horiba Micros 60, patient testing log sheets, Quality Control (QC) records and an interview with the technical consultant, the laboratory failed to perform and document a complete validation study to verify the performance specification for the hematology analyzer. FINDINGS: 1. The technical consultant confirmed on August 25, 2021 at approximately 3:00 PM, the surveyor's findings that the laboratory failed to perform and document a complete validation study to verify the performance specification for the ABX Horiba Micros 60 hematology analyzer, prior to patient testing. 2. The laboratory installed the new hematology analyzer on 7/3/21 and performed precision, linearity, calibration and training on 7/27/2021 but did not perform the correlation method for accuracy. 3. The laboratory performed and documented the 3 levels of QC from 8/6/21 through 3/24/21 a. the patient log sheets recorded the patient testing was implemented on 8/6/21 through 8/24/21. b. Approximately 273 patient samples were tested and reported from 8/6/21 through 8/24/21.