Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2039517	09/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Coorporation Of America	263 Medical Park Boulevard, Petersburg, VA	

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
D0000	An announced CLIA recertification survey was conducted at LabCorp-VCI Petersburg on September 19, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 review of policies and procedures, hematology calibration records, maintenance records, and interviews, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) patient testing according to their policy from January 9, 2019 to the date of the survey on September 19, 2019. Findings include: 1. Review of the laboratory's procedure manual revealed a quality assurance policy that stated "hematology calibrations will be completed at least every 6 months and after major maintenance as needed". 2. Review of the hematology service maintenance logs revealed a preventative maintenance document (form title: Beyond Care) that stated, "evidence based preventative maintenance" procedures were completed by a Sysmex field service engineer on 7/5/19. 3. Review

	of the hematology analyzer, Sysmex XS 1000 IC (Serial Number A1115), calibration records from 10/19/17 up to 9/19/19 revealed the following calibration performance records: 10/19/17, 1/19/18, 7/12/18, and 1/9/19. The lab inspector requested to review additional calibration records for the timeframe of 7/5/19 to 9/19/19. No additional calibration documentation was available. The technical supervisor stated at approximately 1:00 PM "The calibration wasn't performed at 6 months. Sysmex couldn't give me a reason for the postponement. They just stated it was postponed". 4. In an exit interview with the Quality Manager at approximately 3:30 PM, the above findings were confirmed.