Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2039517	12/15/2021
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 the Lab Corp- VCI Petersburg on 12/15/21 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to maintain documentation of the attestation statement event for one of six events in 2020 and testing personnel (TP) failed to sign the attentation statement for one of six events in 2020. Findings include: 1. Review of the available American Proficiency Institute (API) PT records revealed lack of documentation for the following events: 2020- Hematology third event- lack of documentation of the attestation statement. 2020- Core Chemistry third event- TP failed to sign the attestation statement. 2. An exit interview with the technical supervisor on 12/15/21 at approximately 12:30 PM confirmed the findings.

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and interview technical supervisor (TS), the laboratory failed to retain the "e-Check (XS) quality control" manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for 13 of 13 lot numbers utilized from 12/01/19 and up to 10/17/21. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts from 12/01/19 and up to 10/17/21 revealed the laboratory received and utilized 13 lot numbers of the "e-Check (XS) quality control". The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: 9267, 9323, 0014, 0070, 0126, 0182, 0238, 0294, 0350, 1040, 1096, 1152, and 1208. 2. An exit interview with the TS on 12/15/21 at approximately 12:30 PM confirmed the findings.