Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0655109	11/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	1126 North Church Street, Suite 104, Greensboro, NC	

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
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 review of the laboratory's policies and procedures, review of validation records, and interview with the GS (general supervisor) 11/3/21, the laboratory failed to verify the performance specifications for the BD Veritor Plus analyzer prior to testing patient specimens. Review of the laboratory's policies and procedures revealed the laboratory uses the BD Veritor Plus analyzer to perform Influenza A/Influenza B and RSV (respiratory syncytial virus) tests. Review of validation records revealed that the instrument was validated in February 2019 at the laboratory's parent facility. The validation was reviewed and the instrument was approved for use 9/28/19 by the discipline director at the parent laboratory. Upon receipt of the analyzer 3/2/20, the laboratory performed a verification cartridge check. The verification cartridge check was acceptable, and the analyzer was approved for use by the GS on 3/2/20. There was no documentation available to indicate that the laboratory performed any additional testing to verify the performance of the analyzer prior to testing patient specimens. During interview at approximately 4:40 p.m., the GS confirmed that the laboratory performed only the cartridge verification check prior to testing patients. She stated they were told by their parent laboratory that the validation had already been done and no additional testing was needed.