Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2179256	02/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	3355 Douglas Road - Room# 726, South Bend, IN	

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
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to check the positive and negative reactivity of hematoxylin and eosin (H&E) stain for 5 of 9 dates of use reviewed. Findings included: 1. Review of patient test reports indicated the following patient histopathology slides were reported as follows: a. Patient #4; 10-28-2020 b. Patient #5; 10-13-2020 c. Patient #7; 12-2-2020 d. Patient #10; 12-22-2020 e. Patient #11; 12-11-2020 2. Review of stain quality control (QC) documentation indicated the laboratory did not have documentation of positive and negative reactivity for the H&E stain on the following dates: 10-13-2020; 10-28-2020; 12-2-2020; 12-11-2020; and 12-22-2020. 3. In interview on 2-3-2021 at 11:17 AM, SP1, Anatomic Pathology Quality Management Director, indicated there was no QC documentation of the positive and negative reactivity for H&E stains on the following dates: 10-13-2020; 10-28-2020; 12-2-2020; 12-11-2020; and 12-22-2020. SP1 further indicated the test report date was the same as the date the slides were read. 4. Review of "Test Methodology And Annual Test Volume Log" (Enclosure I), signed by the laboratory director on 1-07-2021, indicated the laboratory performed 4700 H&E histology cases per year.