Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0355012	03/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	12772 Hamilton Crossing Blvd - Suite B, Carmel, 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
D0000	A proficiency testing desk review survey was completed on 3/31/2025. It was determined that the following condition-level deficiencies existed: D2016 - 42 C.F.R. 493.803 Condition: Successful participation proficiency testing D6076- 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and

	emails from the Technical Consultant (SP-1) on 03/24/2025, the laboratory failed to achieve satisfactory performance in two consecutive testing events (Event 3 of 2024 and Event 1 of 2025) resulting in unsuccessful participation in the specialty of Hematology and the analyte of cell identification in 2024 and 2025. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 3/21/2025, the laboratory failed to achieve satisfactory performance in two consecutive testing events (Event 3 of 2024 and Event 1 of 2025) resulting in unsuccessful participation in the specialty of Hematology and the analyte of cell identification in 2024 and 2025. Findings included: 1. Review of the "CASPER Report 0155D," run date 3/14/2025 indicated a score of 0% for event 3 2024, and 60% for event 1 2025 in the specialty of Hematology for the analyte of cell identification as reported by CAP. 2. Upon request for information on PT for 2024 and 2025 for cell identification, via email on 3/21 /2025 at 4:12 pm, SP-1 (Technical Consultant) provided the documents "Original Evaluation BCP-C 2024 Blood Cell ID" and "Original Evaluation BCP-A 2025 Blood Cell ID". 3. Review of the CAP Proficiency Testing Performance Evaluation report "Original Evaluation BCP-C 2024 Blood Cell ID", signed by the SP-2 (laboratory director) on 3/17/2025, detailed the following on page 2 of 2: a.) Proficiency Event 2024 3 had a score of 0/5 0% for cell identification. b.) Proficiency Event 2024 3 had a score of 0/5 0% for Hematology. b.) The current event performance interpretation was "unsatisfactory" for both cell identification and hematology. 4. Review of the CAP Proficiency Testing Performance Evaluation report " Original Evaluation BCP-A 2025 Blood Cell ID ", signed by SP-2 on 2/28/2025, detailed the following on page 3 of 3: a.) Proficiency Event 2024 3 had a score of 0/5 0% for cell identification. b.) Proficiency Event 2024 3 had a score of 0/5 0% for Hematology. c.) Proficiency Event 2025 1 had a score of 3/5 60% for cell identification d.) Proficiency Event 2025 1 had a score of 3/5 60% for Hematology. e.) The current event performance interpretation was "unsatisfactory" for both cell identification and hematology. f.) The "Cumulative CLIA '88 Performance Interpretation" was "unsuccessful" for cell identification and hematology.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, and CASPER Report

	0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 3/21/2025, the laboratory director failed to ensure that the laboratory successfully participated in two consecutive testing events (Event 3 of 2024 and Event 1 of 2025) resulting in unsuccessful participation in the specialty of Hematology and the analyte of cell identification in 2024 and 2025. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 3/21/2025, the laboratory director failed to ensure that the laboratory successfully participated in an Health and Human Services (HHS) approved testing program for the specialty Hematology and the analyte cell identification in 2024 and 2025. Refer to D2130.