

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2171145	(X3) Date Survey Completed 01/28/2026
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 4455 Edison Lakes Pkwy, Mishawaka, 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 PT Desk Review survey was completed on 1-28-2026. The following condition-level deficiencies were found to be out of compliance: D2016- 42 C.F.R. 493.803 Condition: Successful participation (proficiency testing)
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on the proficiency testing desk review (PTDR) of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system and phone interview with SP-01 (Technical Consultant) on 1-23-2026 at 11:30 am, the laboratory failed to achieve satisfactory performance for two consecutive College of American Pathologists (CAP) testing events in 2025 (2nd Event =0% and 3rd Event =0%)</p>

resulting in unsuccessful participation for the analyte(s) PH, PO2 and PCO2. Refer to D2096. Legend: CAP= College of American Pathologists, SP= Staff Person, PH=Potential of Hydrogen, PO2= Partial Pressure of Oxygen, PCO2= Partial Pressure of Carbon Dioxide.

D2089

ROUTINE CHEMISTRY
CFR(s): 493.841(c)

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on the proficiency testing desk review (PTDR) of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system and phone interview with SP-01 (Technical Consultant) on 1-23-2026 at 11:30 am, the laboratory failed to participate in two consecutive CAP testing events in 2025 (2nd Event =0% and 3rd Event =0%) resulting in unsatisfactory performance and a score of 0 for the analyte(s) PH, PO2 and PCO2. Findings include: 1. Review of CASPER report 0155D indicated the following unsuccessful scores for the analytes PH, PO2, PCO2 in the specialty of Blood Gas. a. Event 2-2025: PH, PO2, and PCO2 = 0% b. Event 3-2025: PH, PO2, and PCO2 = 0% 2. In an interview on 1-23-2026 at 11:30 am, SP-01 indicated they did not submit proficiency testing results for the CAP proficiency test events (2nd Event =0% and 3rd Event =0%) for the analytes PH, PO2 and PCO2 listed on the CASPER report 0155D. Legend: CAP= College of American Pathologists, SP= Staff Person, PH=Potential of Hydrogen, PO2= Partial Pressure of Oxygen, PCO2= Partial Pressure of Carbon Dioxide.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on the proficiency testing desk review (PTDR) of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system and phone interview with SP-01 (Technical Consultant) on 1-23-2026 at 11:30 am, the laboratory failed to achieve satisfactory performance for two consecutive CAP testing events in 2025 (2nd Event =0% and 3rd Event =0%) resulting in unsuccessful participation for the analyte(s) PH, PO2 and PCO2 . Refer to D2089