

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2155134	(X3) Date Survey Completed 01/22/2025
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 380 W County Road D, New Brighton, MN	
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	. The Laboratory Corporation of America Holdings laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on January 16, 2025. The following condition-level deficiency was cited: 493.1453 Laboratories Performing High Complexity Testing: Clinical Consultant The following standard-level deficiency was cited: 493.1455 Clinical Consultant Qualifications .
D6134	<p>CLINICAL CONSULTANT CFR(s): 493.1453</p> <p>The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on review of education credentials and documents and email correspondence with laboratory personnel, the laboratory failed to ensure personnel performing Clinical Consultant responsibilities meet the qualification requirements of 493.1455. Findings are as follows: The laboratory failed to ensure the Clinical Consultant (CC) met the qualification criteria required to perform CC responsibilities. See D6135. .</p>
D6135	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed</p>

to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

. Based on document review and email correspondence with laboratory personnel, the laboratory failed to ensure the Clinical Consultant (CC) met the qualification criteria required to perform CC responsibilities in 2024 and 2025. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 AM on 1/16/2025. 2. Employee 1 (EE1) was listed on the Laboratory Personnel Report (CLIA), Form CMS-209, as holding the roles of Laboratory Director and Clinical Consultant. 3. Laboratory records indicated EE1 was solely responsible for all CC activities from 12/28/24 to date of survey. 4. The following education document was not found during review of EE1 personnel records on date of survey: -20 CE credit hours in laboratory practice 5. In an email at 2:09 PM on 1/22/25, the GS confirmed that EE1 had not completed the required credit hours. .