

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0693066	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier DeKalb County Board Of Health	Street Address, City, State 445 Winn Way, Room 167, Decatur, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 22, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist documentation for 2019, 2020 and 2021(January- September 2021). 2. During an interview with the Laboratory Director(CMS 209) on September 22, 2021 at 1:00 PM, in the conference room, confirmed the lack of QA checklist documentation for 2019, 2020 and 2021(January-September 2021).</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on laboratory review and interview with the laboratory director(LD), the LD failed to perform and document the quality assessment as required for the laboratory. Findings include: 1. Document review of the quality assessment revealed that the LD did not assure the implementation of a quality assessment procedure for 2019, 2020, and thus far 2021. 2. During an interview with LD on September 22, 2021 at approximately 12:20 PM in a conference room, confirmed the lack of quality assessment review for 2019, 2020, and thus far 2021.