

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0924021	<b>(X3) Date Survey Completed</b>  06/23/2022
<b>Name of Provider or Supplier</b>  Morehouse School Of Medicine	<b>Street Address, City, State</b>  720 Westview Drive, Sw, Room F-126, Atlanta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on June 23, 2022. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> 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 on a monthly or quarterly basis per their QA guidelines as required. The Findings include: 1. Laboratory QA documents review revealed the laboratory did not have a monthly or quarterly quality checklists in 2020 thru date of survey (06/23/2022). 2. Daily maintenance logs including: Room Temperature, Humidity, Refrigerator and Freezer logs had no normal ranges or location documented. 3. No evidence of maintenance logs review in 2020 thru date of survey (06/23/2022). 3. An interview with the Technical Supervisor (TS), on 06/23/2022, at 12:25 PM in the break room confirmed the lack of adequate QA checklist and standard maintenance logs for the laboratory in 2020 thru date of survey (06/23/2022).</p>
<b>D6022</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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 director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Quality Assurance(QA) documents review and staff interview, the Lab Director(LD) failed to ensure that proper QA guidelines were followed including regular review of instrument Quality Control (QC) and (QA) data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. (QC) and (QA) documents review revealed the laboratory director did not review maintenance or (QC) logs to identify and correct problems in the laboratory as they occur in 2020 thru date of survey ( 06/23 /2022). 2. An interview with the Technical Supervisor(TS) in the break room on 06/23 /2022, at approximately 12:50 PM, confirmed the LD did not review the aforementioned (QC) and (QA) data in 2020 thru the date of survey ( 06/23/2022).